

US3112030 (Prod: Medical Center For Clinical Research - M3 Wake Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:11:47

All time stamps listed in this document are displayed in GMT

US3112030

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 20:23:00

Generated On: 09 Jun 2021 15:11:47

Participant ID

US3112030

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

US3112030

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 16:37:40

Generated On: 09 Jun 2021 15:11:47

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 JUL 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3112030

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 16:37:39

Generated On: 09 Jun 2021 15:11:47

Date of Birth (MMM yyyy)	(b) (6) 1949
Age	71
Age Units	YEARS
Age (Derived)	71
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	True
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 16:37:39

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Date of Informed Consent (*dd MMM yyyy*) 30 JUL 2020

Month and Year of Informed Consent (derived) JUL 2020

Year of Informed Consent (derived) 2020

Protocol Version Amendment 1 ☒
Amendment 2 ☐
Amendment 3 ☐
Amendment 4 ☐
Amendment 5 ☐

Was participant enrolled in the study? Yes ☒
No ☐

If No, indicate reason for screen fail Withdrew Consent ☐
Inclusion/Exclusion ☐
Cohort Full ☐
Other ☐

If reason for screen fail is Other, specify _____
Was this participant screened previously? Yes ☐
No ☒

If Yes, previous participant number _____
Enrollment Trigger 1

US3112030

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 16:37:39

Generated On: 09 Jun 2021 15:11:47

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 16:37:40

Generated On: 09 Jun 2021 15:11:47

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 02 Apr 2021 20:23:27

Generated On: 09 Jun 2021 15:11:47

Condition	BILATERAL DIABETIC RETINOPATHY
Start date (dd MMM yyyy)	UN AUG 2007
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2007
Start Year (derived)	2007
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 02 Apr 2021 20:23:27

Generated On: 09 Jun 2021 15:11:47

Condition	OBSTRUCTIVE SLEEP APNEA
Start date (dd MMM yyyy)	UN JAN 1993
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 1993
Start Year (derived)	1993
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 02 Apr 2021 20:23:27

Generated On: 09 Jun 2021 15:11:47

Condition	MODERATE ASTHMA
Start date (dd MMM yyyy)	UN APR 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)	APR 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 02 Apr 2021 20:23:27

Generated On: 09 Jun 2021 15:11:47

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 02 Apr 2021 20:23:27

Generated On: 09 Jun 2021 15:11:47

Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 02 Apr 2021 20:23:27

Generated On: 09 Jun 2021 15:11:47

Condition	BILATERAL FEET PERIPHERAL SENSORY NEUROPATHY
Start date (dd MMM yyyy)	UN MAR 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)	MAR 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 02 Apr 2021 20:23:27

Generated On: 09 Jun 2021 15:11:47

Condition	ERECTILE DYSFUNCTION
Start date (dd MMM yyyy)	UN JUL 2004
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)	JUL 2004
Start Year (derived)	2004
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 02 Apr 2021 20:23:27

Generated On: 09 Jun 2021 15:11:47

Condition	BENIGN PROSTATIC HYPERPLASIA
Start date (dd MMM yyyy)	UN JAN 2009
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 2012
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	JUL 2012
Stop Year (derived)	2012

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 02 Apr 2021 20:23:27

Generated On: 09 Jun 2021 15:11:47

Condition	OVERACTIVE BLADDER
Start date (dd MMM yyyy)	UN DEC 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)	DEC 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 02 Apr 2021 20:23:27

Generated On: 09 Jun 2021 15:11:47

Condition	SCOLIOSIS T-SPINE
Start date (dd MMM yyyy)	UN APR 1988
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	APR 1988
Start Year (derived)	1988
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 02 Apr 2021 20:23:27

Generated On: 09 Jun 2021 15:11:47

Condition	BILATERAL KNEE OSTEOARTHRITIS
Start date (dd MMM yyyy)	UN SEP 1987
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)	SEP 1987
Start Year (derived)	1987
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 02 Apr 2021 20:23:27

Generated On: 09 Jun 2021 15:11:47

Condition	TYPE II DIABETES
Start date (dd MMM yyyy)	UN APR 1988
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	APR 1988
Start Year (derived)	1988
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 02 Apr 2021 20:23:27

Generated On: 09 Jun 2021 15:11:47

Condition	HERNIATED C5 AND C6
Start date (dd MMM yyyy)	UN JUN 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)	JUN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 02 Apr 2021 20:23:27

Generated On: 09 Jun 2021 15:11:47

Condition	TRANSURETHRAL RESECTION OF THE PROSTATE
Start date (dd MMM yyyy)	UN JUL 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 JUL 2012
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2012
Start Year (derived)	2012
Stop Month and Year (derived)	JUL 2012
Stop Year (derived)	2012

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 02 Apr 2021 20:23:27

Generated On: 09 Jun 2021 15:11:47

Condition	LEFT TOTAL KNEE REPLACEMENT
Start date (dd MMM yyyy)	31 JUL 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)	31 JUL 2019
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JUL 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 02 Apr 2021 20:23:27

Generated On: 09 Jun 2021 15:11:47

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

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 02 Apr 2021 20:23:27

Generated On: 09 Jun 2021 15:11:47

Condition	HAY FEVER
Start date (dd MMM yyyy)	UN UNK 2009
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 2009
Start Year (derived)	2009
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 02 Apr 2021 20:23:27

Generated On: 09 Jun 2021 15:11:47

Condition	CONSTIPATION
Start date (dd MMM yyyy)	UN UNK 2009
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 2009
Start Year (derived)	2009
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 02 Apr 2021 20:23:27

Generated On: 09 Jun 2021 15:11:47

Condition	HYPERTENSION
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 (20)

Data signed: (b) (4) 02 Apr 2021 20:23:27

Generated On: 09 Jun 2021 15:11:47

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

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Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 02 Apr 2021 20:23:27

Generated On: 09 Jun 2021 15:11:47

Condition	INTERMITTENT SKIN RASH L SHOULDER
Start date (dd MMM yyyy)	UN FEB 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)	FEB 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (22)

Data signed: (b) (4) 02 Apr 2021 20:23:27

Generated On: 09 Jun 2021 15:11:47

Condition	TOOTH CAVITY
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	11 DEC 2020
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	DEC 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 16:37:40

Generated On: 09 Jun 2021 15:11:47

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	30 JUL 2020
Time of assessment (<i>00:00-23:59</i>)	11:56 (24 HR)
Vital Signs Date and Time (derived)	30 JUL 2020 11:56
Height (<i>xxx.x</i>)	163 cm
Weight (<i>xxx.x</i>)	83.2 kg
BMI (<i>xxx.x</i>)	31.31469 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 16:37:40

Generated On: 09 Jun 2021 15:11:47

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 JUL 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 16:37:40

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

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) 19 Feb 2021 16:37:40

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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	RESIDENT IN A COMMUNITY WITH ONGOING PERSON TO PERSON TRANSMISSION

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:36:17

Generated On: 09 Jun 2021 15:11:47

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 JUL 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 12 Feb 2021 20:36:17

Generated On: 09 Jun 2021 15:11:47

What was the date of randomization? (dd MMM yyyy) 30 JUL 2020

What was the participant's randomization number? 184249

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 20:36:17

Generated On: 09 Jun 2021 15:11:47

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) 12 Feb 2021 20:36:17

Generated On: 09 Jun 2021 15:11:47

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)	30 JUL 2020
Time of assessment (00:00-23:59)	11:56 (24 HR)
Vital Signs Date and Time (derived)	30 JUL 2020 11:56
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	072 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 20:36:17

Generated On: 09 Jun 2021 15:11:47

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)	30 JUL 2020
Time of assessment (00:00-23:59)	14:00 (24 HR)
Vital Signs Date and Time (derived)	30 JUL 2020 14:00
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	076 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:36:17

Generated On: 09 Jun 2021 15:11:47

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) 12 Feb 2021 20:36:17

Generated On: 09 Jun 2021 15:11:47

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) 30 JUL 2020

What was the treatment time? (00:00-23:59) 13:29 (24 HR)

Treatment Date and Time (derived) 30 JUL 2020 13:29

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:36:17

Generated On: 09 Jun 2021 15:11:47

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

30 JUL 2020

Collection time (00:00-23:59)

13:00 (24 HR)

Collection date and time (derived)

30 JUL 2020 13:00

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 20:36:17

Generated On: 09 Jun 2021 15:11:47

Collection date (dd MMM yyyy)			30 JUL 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:45	30 JUL 2020 12:45
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:36:17

Generated On: 09 Jun 2021 15:11:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 JUL 2020 14:05

PC Open Date & Time

30 JUL 2020 13:49

PC Close Date & Time

30 JUL 2020 16:19

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	30 JUL 2020 20:56
PC Open Date & Time	30 JUL 2020 17:14
PC Close Date & Time	31 JUL 2020 11:59

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

31 JUL 2020 13:11

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 AUG 2020 12:12

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:11:47

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 ☒

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 02 AUG 2020 20:43

PC Open Date & Time 02 AUG 2020 12:00

PC Close Date & Time 03 AUG 2020 11:59

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:11:47

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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 AUG 2020 12:14

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:11:47

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

97.8 °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

04 AUG 2020 14:27

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:11:47

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 AUG 2020 22:46

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 JUL 2020 14:08

PC Open Date & Time

30 JUL 2020 13:49

PC Close Date & Time

30 JUL 2020 16:19

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

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

30 JUL 2020 20:59

PC Open Date & Time

30 JUL 2020 17:14

PC Close Date & Time

31 JUL 2020 11:59

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:11:47

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

31 JUL 2020 13:12

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:11:47

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

01 AUG 2020 12:13

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:11:47

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

02 AUG 2020 20:44

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:11:47

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

03 AUG 2020 12:14

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:11:47

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

04 AUG 2020 14:27

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:11:47

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

05 AUG 2020 22:46

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

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 ☐

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

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

No ☒

Yes ☐

PC Time stamp	30 JUL 2020 14:09
PC Open Date & Time	30 JUL 2020 13:49
PC Close Date & Time	30 JUL 2020 16:19

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

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 ☐

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

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

No ☒

Yes ☐

PC Time stamp	30 JUL 2020 21:02
PC Open Date & Time	30 JUL 2020 17:14
PC Close Date & Time	31 JUL 2020 11:59

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:11:47

Yes <input type="checkbox"/>	
PC Time stamp	31 JUL 2020 13:13
PC Open Date & Time	31 JUL 2020 12:00
PC Close Date & Time	01 AUG 2020 11:59

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:11:47

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)

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Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:11:47

Yes <input type="checkbox"/>	
PC Time stamp	01 AUG 2020 12:14
PC Open Date & Time	01 AUG 2020 12:00
PC Close Date & Time	02 AUG 2020 11:59

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:11:47

Yes <input type="checkbox"/>	
PC Time stamp	02 AUG 2020 20:45
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:11:47

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 ☒

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:11:47

Yes <input type="checkbox"/>	
PC Time stamp	03 AUG 2020 12:15
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:11:47

Yes <input type="checkbox"/>	
PC Time stamp	04 AUG 2020 14:28
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:11:47

Yes <input type="checkbox"/>	
PC Time stamp	05 AUG 2020 22:49
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3112030

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

DAY 8

Select one response below to indicate the level of your

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 ☐

PC Time stamp

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3112030

Folder: Diary Dose 1 (1)

Form: Nausea_Day(9)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

DAY 9

Select one response below to indicate the level of your

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 ☐

PC Time stamp

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3112030

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3112030

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3112030

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:30:48

Generated On: 09 Jun 2021 15:11:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3112030

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:30:48

Generated On: 09 Jun 2021 15:11:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112030

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:30:48

Generated On: 09 Jun 2021 15:11:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3112030

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:30:48

Generated On: 09 Jun 2021 15:11:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112030

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:30:48

Generated On: 09 Jun 2021 15:11:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3112030

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:30:48

Generated On: 09 Jun 2021 15:11:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112030

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:36:17

Generated On: 09 Jun 2021 15:11:47

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3112030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 20:36:17

Generated On: 09 Jun 2021 15:11:47

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)	27 AUG 2020
Time of assessment (00:00-23:59)	11:20 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 11:20
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 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)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3112030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 20:36:17

Generated On: 09 Jun 2021 15:11:47

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)	27 AUG 2020
Time of assessment (00:00-23:59)	12:45 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 12:45
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3112030

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:36:17

Generated On: 09 Jun 2021 15:11:47

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 AUG 2020

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

US3112030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 20:36:17

Generated On: 09 Jun 2021 15:11:47

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) 27 AUG 2020

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

Treatment Date and Time (derived) 27 AUG 2020 12:12

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

US3112030

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:36:17

Generated On: 09 Jun 2021 15:11:47

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

Collection date (dd MMM yyyy)	27 AUG 2020
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Collection time (00:00-23:59)	11:05 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	27 AUG 2020 11:05
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US3112030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 12 Feb 2021 20:36:17

Generated On: 09 Jun 2021 15:11:47

Collection date (dd MMM yyyy)			27 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:36	27 AUG 2020 11:36
Nasopharyngeal Swab 2	No		

US3112030

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:36:17

Generated On: 09 Jun 2021 15:11:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

27 AUG 2020 12:51

PC Open Date & Time

27 AUG 2020 12:32

PC Close Date & Time

27 AUG 2020 15:02

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.4 °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	27 AUG 2020 23:10
PC Open Date & Time	27 AUG 2020 15:57
PC Close Date & Time	28 AUG 2020 11:59

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:11:47

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

28 AUG 2020 13:10

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:11:47

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

97.8 °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

29 AUG 2020 12:01

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:11:47

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

96.8 °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

30 AUG 2020 12:07

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 12:14

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:11:47

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

97.0 °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

01 SEP 2020 12:44

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:11:47

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 ☒

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 02 SEP 2020 13:45

PC Open Date & Time 02 SEP 2020 12:00

PC Close Date & Time 03 SEP 2020 11:59

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 12:53

PC Open Date & Time

27 AUG 2020 12:32

PC Close Date & Time

27 AUG 2020 15:02

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

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

27 AUG 2020 23:11

PC Open Date & Time

27 AUG 2020 15:57

PC Close Date & Time

28 AUG 2020 11:59

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:11:47

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

28 AUG 2020 13:10

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:11:47

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

29 AUG 2020 12:02

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:11:47

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

30 AUG 2020 12:07

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:11:47

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

31 AUG 2020 12:14

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:11:47

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

01 SEP 2020 12:45

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:11:47

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

02 SEP 2020 13:45

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

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 ☐

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

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

No ☒

Yes ☐

PC Time stamp	27 AUG 2020 12:54
PC Open Date & Time	27 AUG 2020 12:32
PC Close Date & Time	27 AUG 2020 15:02

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

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 ☐

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

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

No ☒

Yes ☐

PC Time stamp	27 AUG 2020 23:12
PC Open Date & Time	27 AUG 2020 15:57
PC Close Date & Time	28 AUG 2020 11:59

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:11:47

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 13:11
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:11:47

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 12:04
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

117 of 3436

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:11:47

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 12:09
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:11:47

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 12:15
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:11:47

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)

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:11:47

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 12:45
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:11:47

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 13:46
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3112030

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 21:30:48

Generated On: 09 Jun 2021 15:11:47

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 3 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3112030

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 21:30:48

Generated On: 09 Jun 2021 15:11:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112030

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:36:17

Generated On: 09 Jun 2021 15:11:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3112030

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:36:17

Generated On: 09 Jun 2021 15:11:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112030

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 20:36:17

Generated On: 09 Jun 2021 15:11:47

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

US3112030

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:36:17

Generated On: 09 Jun 2021 15:11:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112030

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 20:36:17

Generated On: 09 Jun 2021 15:11:47

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 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	VISIT3

US3112030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Feb 2021 20:36:17

Generated On: 09 Jun 2021 15:11:47

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 SEP 2020
Time of assessment (00:00-23:59)	13:23 (24 HR)
Vital Signs Date and Time (derived)	25 SEP 2020 13:23
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	061 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3112030

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 20:36:17

Generated On: 09 Jun 2021 15:11:47

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.

US3112030

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Feb 2021 20:36:17

Generated On: 09 Jun 2021 15:11:47

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	25 SEP 2020
Collection time (00:00-23:59)	13:45 (24 HR)
Collection date and time (derived)	25 SEP 2020 13:45

US3112030

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 20:36:17

Generated On: 09 Jun 2021 15:11:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 SEP 2020 00:02:37
Patient Cloud Open Date & Time	29 SEP 2020 00:01
Patient Cloud Close Date & Time	03 OCT 2020 23:59

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

08 OCT 2020 12:01:21

Patient Cloud Open Date & Time

06 OCT 2020 00:01

Patient Cloud Close Date & Time

10 OCT 2020 23:59

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 OCT 2020 15:13:54

Patient Cloud Open Date & Time

13 OCT 2020 00:01

Patient Cloud Close Date & Time

17 OCT 2020 23:59

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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 checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	29 OCT 2020 22:04:10
Patient Cloud Open Date & Time	27 OCT 2020 00:01
Patient Cloud Close Date & Time	31 OCT 2020 23:59

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	03 NOV 2020 00:16:19
Patient Cloud Open Date & Time	03 NOV 2020 00:01
Patient Cloud Close Date & Time	07 NOV 2020 23:59

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT	DAY 106
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	10 NOV 2020 19:50:56
Patient Cloud Open Date & Time	10 NOV 2020 00:01
Patient Cloud Close Date & Time	14 NOV 2020 23:59

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

DAY 113

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 NOV 2020 01:37:46

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

21 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2020 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

30 NOV 2020 19:05:16

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

07 DEC 2020 14:40:54

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 DEC 2020 13:40:50

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

20 DEC 2020 18:32:44

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 DEC 2020 18:49:42

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

05 JAN 2021 18:22:38

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

10 JAN 2021 19:29:06

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

18 JAN 2021 12:14:01

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 JAN 2021 12:16:48

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

01 FEB 2021 12:08:54

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

08 FEB 2021 12:01:06

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 FEB 2021 01:01:15

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

20 FEB 2021 00:47:47

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

27 FEB 2021 08:05:17

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

08 MAR 2021 10:11:26

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

15 MAR 2021 12:31:39

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

20 MAR 2021 00:03:10

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

28 MAR 2021 17:12:29

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

03 APR 2021 17:27:37

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

10 APR 2021 01:45:09

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 13:36:24

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

DAY 271

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 APR 2021 00:25:59

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

Date and time of submission

01 MAY 2021 00:07:38

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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 ☐

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

DAY 299

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

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

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

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

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

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

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

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

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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 ☐

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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 ☐

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 JUN 2021 00:01
Patient Cloud Close Date & Time	09 JUN 2021 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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"/>

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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 ☐

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

DAY 334

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

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

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

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

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

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

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

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

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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"/>

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

DAY 348

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

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

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

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

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

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

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 ☐

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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 ☐

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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 ☐

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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 ☐

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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 ☐

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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°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 ☐

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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 ☐

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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"/>

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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"/>

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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 ☐

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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="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"/>

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

Patient Cloud Open Date & Time	25 SEP 2021 00:01
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Patient Cloud Close Date & Time	29 SEP 2021 23:59
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US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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 ☐

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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"/>

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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 ☐

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 OCT 2021 00:01
Patient Cloud Close Date & Time	27 OCT 2021 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

DAY 460

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

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

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

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

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

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

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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 ☐

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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 <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"/>

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

DAY 488

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

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

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

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

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

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

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

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

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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"/>

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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 ☐

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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 ☐

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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 ☐

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

[Patient Cloud Open Date & Time](#)

25 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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 ☐

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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 ☐

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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 ☐

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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 ☐

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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 ☐

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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 ☐

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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 ☐

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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 ☐

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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 ☐

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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 ☐

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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 ☐
Yes ☐

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

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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"/>

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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"/>

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

DAY 628

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

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

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

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

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

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

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

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

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 APR 2022 00:01
Patient Cloud Close Date & Time	27 APR 2022 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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 ☐

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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 ☐

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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 ☐

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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 ☐

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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"/>

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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 ☐

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUN 2022 00:01
Patient Cloud Close Date & Time	29 JUN 2022 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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 ☐

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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 ☐
Yes ☐

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

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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"/>

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

DAY 733

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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 ☐

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

Patient Cloud Open Date & Time	13 AUG 2022 00:01
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Patient Cloud Close Date & Time	17 AUG 2022 23:59
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US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

Patient Cloud Open Date & Time	27 AUG 2022 00:01
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Patient Cloud Close Date & Time	31 AUG 2022 23:59
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US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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 ☐

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

[Patient Cloud Open Date & Time](#)

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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 ☐

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 OCT 2022 00:01
Patient Cloud Close Date & Time	05 OCT 2022 23:59

US3112030

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:11:47

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		08 MAR 2021 10:12:31

US3112030

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 19:40:25

Generated On: 09 Jun 2021 15:11:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3112030

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 19:40:25

Generated On: 09 Jun 2021 15:11:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112030

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:23:03

Generated On: 09 Jun 2021 15:11:47

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 24 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3112030

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:23:03

Generated On: 09 Jun 2021 15:11:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112030

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:23:03

Generated On: 09 Jun 2021 15:11:47

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3112030

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:23:03

Generated On: 09 Jun 2021 15:11:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112030

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:23:27

Generated On: 09 Jun 2021 15:11:47

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3112030

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:23:03

Generated On: 09 Jun 2021 15:11:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112030

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:23:27

Generated On: 09 Jun 2021 15:11:47

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

Visit date (dd MMM yyyy)	22 FEB 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3112030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 20:23:27

Generated On: 09 Jun 2021 15:11:47

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 FEB 2021
Time of assessment (00:00-23:59)	13:08 (24 HR)
Vital Signs Date and Time (derived)	22 FEB 2021 13:08
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)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3112030

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:23:27

Generated On: 09 Jun 2021 15:11:47

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.

US3112030

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:23:27

Generated On: 09 Jun 2021 15:11:47

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 22 FEB 2021

Collection time (00:00-23:59) 13:20 (24 HR)

Collection date and time (derived) 22 FEB 2021 13:20

US3112030

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:23:27

Generated On: 09 Jun 2021 15:11:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112030

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:23:27

Generated On: 09 Jun 2021 15:11:47

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3112030

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:23:27

Generated On: 09 Jun 2021 15:11:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112030

Folder: Safety Call Day 269 (1)

Form: Safety Call

Data signed: (b) (4) 23 Apr 2021 21:01:30

Generated On: 09 Jun 2021 15:11:47

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3112030

Folder: Safety Call Day 269 (1)

Form: Continuing

Data signed: (b) (4) 23 Apr 2021 21:01:30

Generated On: 09 Jun 2021 15:11:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112030

Folder: Safety Call Day 299 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

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

US3112030

Folder: Safety Call Day 299 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:47

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3112030

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:11:47

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"/>

US3112030

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:11:47

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3112030

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:23:03

Generated On: 09 Jun 2021 15:11:47

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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US3112030

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

Form: Unblinding

Data signed: (b) (4) 02 Apr 2021 20:23:03

Generated On: 09 Jun 2021 15:11:47

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

US3112030

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 02 Apr 2021 20:23:03

Generated On: 09 Jun 2021 15:11:47

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

US3112030

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 20:23:03

Generated On: 09 Jun 2021 15:11:47

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)	15:10 (24 HR)
Vital Signs Date and Time (derived)	12 JAN 2021 15:10
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)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3112030

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 20:23:03

Generated On: 09 Jun 2021 15:11:47

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)	16:20 (24 HR)
Vital Signs Date and Time (derived)	12 JAN 2021 16:20
Temperature (xxx.x)	98 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

US3112030

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

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:23:03

Generated On: 09 Jun 2021 15:11:47

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.

US3112030

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

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 20:23:03

Generated On: 09 Jun 2021 15:11:47

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) 15:49 (24 HR)

Treatment Date and Time (derived) 12 JAN 2021 15:49

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

What was the frequency of the study treatment dosing? ONCE

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

US3112030

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:23:03

Generated On: 09 Jun 2021 15:11:47

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

Collection date (dd MMM yyyy)	12 JAN 2021
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Collection time (00:00-23:59)	15:20 (24 HR)
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Collection date and time (derived)	12 JAN 2021 15:20
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US3112030

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 20:23:03

Generated On: 09 Jun 2021 15:11:47

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 12 JAN 2021

Collection time (00:00 - 23:59) 15:14

Collection Date and Time (derived) 12 JAN 2021 15:14

US3112030

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

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:23:03

Generated On: 09 Jun 2021 15:11:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112030

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:23:27

Generated On: 09 Jun 2021 15:11:47

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

US3112030

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:23:27

Generated On: 09 Jun 2021 15:11:47

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

US3112030

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:23:03

Generated On: 09 Jun 2021 15:11:47

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

Visit date (dd MMM yyyy)	16 FEB 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	OLD29
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US3112030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 20:23:03

Generated On: 09 Jun 2021 15:11:47

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)	16 FEB 2021
Time of assessment (00:00-23:59)	15:14 (24 HR)
Vital Signs Date and Time (derived)	16 FEB 2021 15:14
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)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG

US3112030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 20:23:03

Generated On: 09 Jun 2021 15:11:47

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	16 FEB 2021
Time of assessment (00:00-23:59)	16:36 (24 HR)
Vital Signs Date and Time (derived)	16 FEB 2021 16:36
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

US3112030

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:23:03

Generated On: 09 Jun 2021 15:11:47

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 FEB 2021

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

US3112030

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 20:23:03

Generated On: 09 Jun 2021 15:11:47

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) 16 FEB 2021

What was the treatment time? (00:00-23:59) 16:05 (24 HR)

Treatment Date and Time (derived) 16 FEB 2021 16:05

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

What was the frequency of the study treatment dosing? ONCE

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

US3112030

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:23:03

Generated On: 09 Jun 2021 15:11:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112030

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:23:27

Generated On: 09 Jun 2021 15:11:47

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3112030

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:23:27

Generated On: 09 Jun 2021 15:11:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3112030

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:23:03

Generated On: 09 Jun 2021 15:11:47

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 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	OLD57

US3112030

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 20:23:03

Generated On: 09 Jun 2021 15:11:47

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 MAR 2021
Time of assessment (00:00-23:59)	15:02 (24 HR)
Vital Signs Date and Time (derived)	17 MAR 2021 15:02
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3112030

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:23:03

Generated On: 09 Jun 2021 15:11:47

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 MAR 2021

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

US3112030

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:23:03

Generated On: 09 Jun 2021 15:11:47

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

Collection date (dd MMM yyyy)	17 MAR 2021
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Collection time (00:00-23:59)	15:20 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	17 MAR 2021 15:20
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US3112030

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Mar 2021 20:16:15

Generated On: 09 Jun 2021 15:11:47

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3112030

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Apr 2021 21:01:30

Generated On: 09 Jun 2021 15:11:47

AEID

Adverse event

DIZZINESS

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)

30 JUL 2020

Start time (00:00-23:59)

13:30 (24 HR)

AE start date and time (derived)

30 JUL 2020 13:30

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

30 JUL 2020

End time (00:00-23:59)

14:10 (24 HR)

AE End Date and Time (derived)

30 JUL 2020 14:10

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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EAB) (1725)

US3112030

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Apr 2021 21:01:30

Generated On: 09 Jun 2021 15:11:47

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

US3112030

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Apr 2021 21:01:30

Generated On: 09 Jun 2021 15:11:47

AEID	USA-US062-2021-MRNA-1273-P30 1000006
Adverse event	PINCHED NERVE SECONDARY TO SURGICAL COMPLICATION
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)	26 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	28 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)	26 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	30 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Apr 2021 21:01:30

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	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:	DIMINISHED BILATERAL GRIP STRENGTH
Narrative	PATIENT UNDERWENT ELECTED CERVICAL DECOMPRESSION RESULTING IN COMPLICATIONS. PENDING MEDICAL RECORDS
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
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[Admitted to ICU Derived \(CSA Programming Field Only\)](#) 0

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 23 Apr 2021 21:01:30

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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 23 Apr 2021 21:01:30

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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 23 Apr 2021 21:01:30

Generated On: 09 Jun 2021 15:11:47

AEID

Adverse event

RHINITIS DUE TO INFECTIVE

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)

26 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

30 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 23 Apr 2021 21:01:30

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 Apr 2021 20:23:02

Generated On: 09 Jun 2021 15:11:47

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication PERIPHERAL SENSORY
NEUROPATHY

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

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	02 SEP 2014	
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 (2)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication PERIPHERAL SENSORY
NEPHROPATHY

Dose per administration 1600

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

QHS

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	02 SEP 2014	
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) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication CRESTOR

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 JAN 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIAC PROPHYLAXIS

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		09 APR 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication ALBUTEROL/ IPRATROPIUM

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 100/200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	04 MAY 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)	4	
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) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication VIAGRA

Prophylaxis Yes ☐
No ☒

Indication ERECTILE DYSFUNCTION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	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) _____		
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 (7)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication HUMULIN R U500

Prophylaxis Yes ☐
No ☒

Indication DMII

Dose per administration 20

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 IN THE MORNING

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) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	14 APR 2014	
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 (8)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication HUMULIN R U500

Prophylaxis Yes ☐
No ☒

Indication DMII

Dose per administration 30

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 MID DAY

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) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	14 AUG 2014	
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 (9)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication HUMULIN R U500

Prophylaxis Yes ☐
No ☒

Indication DMII

Dose per administration 25

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 9PM DAILY

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	14 AUG 2014	
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 (10)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication JANUMET

Prophylaxis Yes ☐
No ☒

Indication DMII

Dose per administration 50/1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	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)	16 JUN 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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 (11)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GERD

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		19 OCT 2012
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication VESICARE

Prophylaxis Yes ☐
No ☒

Indication OAB

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 (12)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 DEC 2018
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication JARDIANCE

Prophylaxis Yes ☐
No ☒

Indication DMII

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 (13)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	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)	27 FEB 2017	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	24 AUG 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
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="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication JARDIANCE

Prophylaxis Yes ☐
No ☒

Indication DMII

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 (14)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	25 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication HUMULIN R U500

Prophylaxis Yes ☐
No ☒

Indication DM 2

Dose per administration 18

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 (15)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	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)	17 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)		19 OCT 2020
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
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="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication CHANTIX

Prophylaxis Yes ☐
No ☒

Indication SMOKING CESSATION AID

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 (16)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication CEFAZOLIN

Prophylaxis Yes ☐
No ☒

Indication PINCHED NERVE

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		23 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)		23 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication CEFAZOLIN

Prophylaxis Yes ☐
No ☒

Indication PINCHED NERVE

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	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)		26 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication CEFAZOLIN

Prophylaxis Yes ☐
No ☒

Indication PINCHED NERVE

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 (19)

Data signed: (b) (4) 28 Apr 2021 21:49:23

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	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 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)		26 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication CEFAZOLIN

Prophylaxis Yes ☐
No ☒

Indication PINCHED NERVE

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Q8HRS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify		INJECTION
Start date (dd MMM yyyy)		26 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)		27 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication CEFAZOLIN

Prophylaxis Yes ☐
No ☒

Indication PINCHED NERVE

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

Q8HRS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify		INJECTION
Start date (dd MMM yyyy)		27 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)		29 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication FERROUS SULFATE

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication FLONASE

Prophylaxis Yes ☐
No ☒

Indication RHINITIS

Dose per administration 50

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

If dose unit is Other, specify MCG

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input checked="" 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)		30 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)		30 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication	BACITRACIN
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	WOUND INFECTION PROPHYLAXIS
Dose per administration	50,000
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	UNITS
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	INJECTION	
Start date (dd MMM yyyy)	26 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)	26 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication BACITRACIN

Prophylaxis Yes ☒
No ☐

Indication WOUND INFECTION
PROPHYLAXIS

Dose per administration 50,000

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	INJECTION	
Start date (dd MMM yyyy)	28 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)	28 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication BUPIVACAINE - EPINEPHRINE
.25%

Prophylaxis Yes ☐
No ☒

Indication PINCHED NERVE

Dose per administration 35

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	INJECTION	
Start date (dd MMM yyyy)	26 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)	26 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication POVIDONE-IODINE 10%

Prophylaxis Yes ☐
No ☒

Indication PINCHED NERVE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	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)		26 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 26 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication VANCOMYCIN

Prophylaxis Yes ☐
No ☒

Indication PINCHED NERVE

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 (28)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify		INJECTION
Start date (dd MMM yyyy)		26 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)		26 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 28 Apr 2021 21:49:23

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Name of Medication VANCOMYCIN

Prophylaxis Yes ☐
No ☒

Indication PINCHED NERVE

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 (29)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify		INJECTION
Start date (dd MMM yyyy)		28 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)		28 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 28 Apr 2021 21:49:23

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Name of Medication FENTANYL

Prophylaxis Yes ☐
No ☒

Indication PINCHED NERVE

Dose per administration 50

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

If dose unit is Other, specify MCG

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 (30)

Data signed: (b) (4) 28 Apr 2021 21:49:23

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	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify		INJECTION
Start date (dd MMM yyyy)		26 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)		26 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication FENTANYL

Prophylaxis Yes ☐
No ☒

Indication PINCHED NERVE

Dose per administration 50

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

If dose unit is Other, specify MCG

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 (31)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify		INJECTION
Start date (dd MMM yyyy)		28 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)		28 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication ZOFRAN

Prophylaxis Yes ☐
No ☒

Indication PINCHED NERVE

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify		INJECTION
Start date (dd MMM yyyy)		26 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)		30 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication ROBAXIN

Prophylaxis Yes ☐
No ☒

Indication PINCHED NERVE

Dose per administration 750

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

If dose unit is Other, specify

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

If frequency is Other, specify

Q8HRS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 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)	28 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication OXYCONTIN

Prophylaxis Yes ☐
No ☒

Indication PINCHED NERVE

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

Q12HRS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	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)		26 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 28 Apr 2021 21:49:23

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Name of Medication PERCOCET

Prophylaxis Yes ☐
No ☒

Indication PINCHED NERVE

Dose per administration 5-325

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

If dose unit is Other, specify

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

If frequency is Other, specify

PRN Q4HRS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	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)	27 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 27 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 28 Apr 2021 21:49:23

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Name of Medication DILAUDID

Prophylaxis Yes ☐
No ☒

Indication PINCHED NERVE

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

Q3HR PRN

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify		INJECTION
Start date (dd MMM yyyy)		26 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)		30 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication CLARITIN

Prophylaxis Yes ☐
No ☒

Indication HAYFEVER

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

Q3HR PRN

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 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)	30 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication CLARITIN

Prophylaxis Yes ☐
No ☒

Indication HAYFEVER

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 (38)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	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)	26 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)		30 OCT 2020
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 (39)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication COLACE

Prophylaxis Yes ☐
No ☒

Indication CONSTIPATION

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	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 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
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 (40)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication GLYCOLAX

Prophylaxis Yes ☐
No ☒

Indication CONSTIPATION

Dose per administration 17

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 (40)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	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)	26 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)	30 OCT 2020	
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 (41)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication SENOKOT

Prophylaxis Yes ☐
No ☒

Indication CONSTIPATION

Dose per administration 17.2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	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)	26 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		30 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication GLUCOSAMINE-SULFATE

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	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)	15 MAR 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 (43)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication DECADRON

Prophylaxis Yes ☐
No ☒

Indication PINCHED NERVE

Dose per administration 8

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

Q6HR

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	INJECTION	
Start date (dd MMM yyyy)	27 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)	29 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication PEPCID

Prophylaxis Yes ☐
No ☒

Indication GERD

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 OCT 2020
Start date completely unknown		False
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		30 OCT 2020
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
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="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication GLUCOSAMINE-CHONDROITIN

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 500/400

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 ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	15 MAR 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 (46)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication HYDROCHLOROTHIAZIDE

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 (46)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	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 2016	
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 (47)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	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 2016	
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 (48)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GERD

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 (48)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	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)	27 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 27 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 (49)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 80

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	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)	26 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	30 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 (50)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication OXYBUTYNIN

Prophylaxis Yes ☐
No ☒

Indication BPH

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 (50)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	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)	26 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	30 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication KENALOG

Prophylaxis Yes ☐
No ☒

Indication SKIN RASH L SHOULDER

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	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)	08 FEB 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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 (52)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication LANTUS

Prophylaxis Yes ☐
No ☒

Indication TYPE 2 DIABETES

Dose per administration 10

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

If dose unit is Other, specify UNIT

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify		INJECTION
Start date (dd MMM yyyy)		27 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)		27 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"/>

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication LANTUS

Prophylaxis Yes ☐
No ☒

Indication TYPE 2 DIABETES

Dose per administration 20

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 (53)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify		INJECTION
Start date (dd MMM yyyy)		28 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)		28 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication BUPIVACAINE-EPINEPHRINE
.5%

Prophylaxis Yes ☐
No ☒

Indication PINCHED NERVE

Dose per administration 15

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 (54)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	INJECTION	
Start date (dd MMM yyyy)	28 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)	28 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication REFRESH PLUS EYE DROPS .5%

Prophylaxis Yes ☐
No ☒

Indication DRY EYES

Dose per administration 1

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

If dose unit is Other, specify DROP

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
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 (56)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication ZYRTEC

Prophylaxis Yes ☐
No ☒

Indication HAYFEVER

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	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 2009	
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 (57)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication PSYLLIUM

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	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)	25 APR 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)	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 (58)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication VOLTAREN 1%

Prophylaxis Yes ☐
No ☒

Indication BILATERAL KNEE PAIN

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		28 JAN 2012
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
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 (59)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

Name of Medication SHINGLES VACCINE

Prophylaxis Yes ☒
No ☐

Indication SHINGLES 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 ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Data signed: (b) (4) 28 Apr 2021 21:49:23

Generated On: 09 Jun 2021 15:11:47

	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)	11 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		11 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3112030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 20:23:02

Generated On: 09 Jun 2021 15:11:47

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3112030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 02 Apr 2021 20:23:02

Generated On: 09 Jun 2021 15:11:47

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
26 OCT 2020	CERVICAL DECOMPRESSION	Medical History	
28 OCT 2020	CORRECTIVE BACK SURGERY	Adverse Event	
11 DEC 2020	TOOTH EXTRACTIONS X3	Medical History	

US3112030

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:11:47

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3112030

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:11:47

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 ☐

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) 23 Apr 2021 21:01:30

Generated On: 09 Jun 2021 15:11:47

SAEID	USA-US062-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TODD
Investigator's Last Name	SIMMONS
Site Address: Street	9040 FRIARS ROAD SUITE 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) 23 Apr 2021 21:01:30

Generated On: 09 Jun 2021 15:11:47

SAEID	USA-US062-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TODD
Investigator's Last Name	SIMMONS
Site Address: Street	9040 FRIARS ROAD SUITE 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	14/JAN/2021 11:54
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

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Data signed: (b) (4) 23 Apr 2021 21:01:30

Generated On: 09 Jun 2021 15:11:47

SAEID	USA-US062-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TODD
Investigator's Last Name	SIMMONS
Site Address: Street	9040 FRIARS ROAD SUITE 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	11/FEB/2021 11:19
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

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Data signed: (b) (4) 23 Apr 2021 21:01:30

Generated On: 09 Jun 2021 15:11:47

SAEID	USA-US062-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TODD
Investigator's Last Name	SIMMONS
Site Address: Street	9040 FRIARS ROAD SUITE 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	23/FEB/2021 13:12
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form (4)

Data signed: (b) (4) 23 Apr 2021 21:01:30

Generated On: 09 Jun 2021 15:11:47

SAEID	USA-US062-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TODD
Investigator's Last Name	SIMMONS
Site Address: Street	9040 FRIARS ROAD SUITE 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	10/MAR/2021 09:34
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

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form (5)

Data signed: (b) (4) 23 Apr 2021 21:01:30

Generated On: 09 Jun 2021 15:11:47

SAEID	USA-US062-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TODD
Investigator's Last Name	SIMMONS
Site Address: Street	9040 FRIARS ROAD SUITE 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	17/MAR/2021 15:41
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

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form (6)

Data signed: (b) (4) 23 Apr 2021 21:01:30

Generated On: 09 Jun 2021 15:11:47

SAEID	USA-US062-2021-MRNA-1273-P301000006
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	TODD
Investigator's Last Name	SIMMONS
Site Address: Street	9040 FRIARS ROAD SUITE 540
Site Address: City	SAN DIEGO
Site Address: State	CA
Site Address: Postal Code	92108
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	19/APR/2021 09:35
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

US3112030 (Prod: Medical Center For Clinical Research - M3 Wake Research)

US3112030

Form: Participant Creation

Generated On: 09 Jun 2021 15:11:47

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'US3112030'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	30 Jul 2020 19:04:13

US3112030

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:11:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	01 Aug 2020 00:47:32

US3112030

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '30 JUL 2020'	RWS_ENDPOINT (b) (4)	30 Jul 2020 19:04:14

US3112030

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:11:47

[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 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'Clinic (Clinic)'	Karen Mylerberg (b) (4)	01 Aug 2020 00:47:32

US3112030

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:11:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered 'SCRN'	System	01 Aug 2020 00:47:32

US3112030

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:11:47

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered (b) (6) 1949'	RWS_ENDPOINT ENDPOINT (b) (4)	30 Jul 2020 19:04:15

US3112030

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:11:47

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '71'	Karen Mylerberg (b) (4)	01 Aug 2020 00:48:28

US3112030

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:11:47

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered 'YEARS'	System	01 Aug 2020 00:48:28

US3112030

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:11:47

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered '71'	System	30 Jul 2020 20:40:33

US3112030

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:11:47

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'Male (M)'	Karen Mylerberg (b) (4)	01 Aug 2020 00:48:28

US3112030

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:11:47

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Karen Mylerberg (b) (4)	01 Aug 2020 00:48:28

US3112030

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:11:47

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	Karen Mylerberg (b) (4)	01 Aug 2020 00:48:28

US3112030

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:11:47

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	Karen Mylerberg (b) (4)	01 Aug 2020 00:48:28

US3112030

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:11:47

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	Karen Mylerberg (b) (4)	01 Aug 2020 00:48:28

US3112030

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:11:47

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	Karen Mylerberg (b) (4)	01 Aug 2020 00:48:28

US3112030

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:11:47

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'I'	Karen Mylerberg (b) (4)	01 Aug 2020 00:48:28

US3112030

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:11:47

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	Karen Mylerberg (b) (4)	01 Aug 2020 00:48:28

US3112030

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:11:47

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered empty.	Karen Mylerberg (b) (4)	01 Aug 2020 00:48:28

US3112030

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:11:47

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	Karen Mylerberg (b) (4)	01 Aug 2020 00:48:28

US3112030

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:11:47

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	Karen Mylerberg (b) (4)	01 Aug 2020 00:48:28

US3112030

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:11:47

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '30 Jul 2020'	Karen Mylerberg (b) (4)	30 Jul 2020 20:40:33

US3112030

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered 'Jul 2020'	System	30 Jul 2020 20:40:33

US3112030

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered '2020'	System	30 Jul 2020 20:40:33

US3112030

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:11:47

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'Amendment 1 (1)'	Karen Mylerberg (b) (4)	30 Jul 2020 20:40:33

US3112030

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	30 Jul 2020 20:40:33

US3112030

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:11:47

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered empty.	Karen Mylerberg (b) (4)	30 Jul 2020 20:40:33

US3112030

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:11:47

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered empty.	Karen Mylerberg (b) (4)	30 Jul 2020 20:40:33

US3112030

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:11:47

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'No (N)'	Karen Mylerberg (b) (4)	30 Jul 2020 20:40:33

US3112030

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:11:47

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	30 Jul 2020 19:04:14

US3112030

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:11:47

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered 'I'	System	30 Jul 2020 20:40:33

US3112030

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	30 Jul 2020 20:40:10

US3112030

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:11:47

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Karen Mylerberg (b) (4)	30 Sep 2020 14:41:26
User entered 'No (N)'	(b) (4)	
	Karen Mylerberg (b) (4)	01 Aug 2020 00:49:20
	(b) (4)	

US3112030

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:11:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User coded data point as SOC: Eye disorders, HLGT: Retina, choroid and vitreous haemorrhages and vascular disorders, HLT: Retinopathies NEC, PT: Diabetic retinopathy, LLT: Diabetic retinopathy - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 14:43:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 14:43:52
Data point term sent to Coder	System	30 Sep 2020 14:42:33
User entered 'bilateral diabetic retinopathy'	Karen Mylerberg (b) (4)	30 Sep 2020 14:41:58

US3112030

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'UN Aug 2007'	Karen Mylerberg (b) (4)	30 Sep 2020 14:41:58

US3112030

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	Karen Mylerberg (b) (4)	30 Sep 2020 14:41:58

US3112030

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:11:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	30 Sep 2020 14:41:58

US3112030

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered empty.	Karen Mylerberg (b) (4)	30 Sep 2020 14:41:58

US3112030

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:11:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	Karen Mylerberg (b) (4)	30 Sep 2020 14:41:58

US3112030

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered 'Aug 2007'	System	30 Sep 2020 14:41:58

US3112030

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered '2007'	System	30 Sep 2020 14:41:58

US3112030

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered empty.	System	30 Sep 2020 14:41:58

US3112030

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered empty.	System	30 Sep 2020 14:41:58

US3112030

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:11:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Obstructive sleep apnea syndrome - version MedDRA\23.0.	Coder Import (b) (4)	30 Sep 2020 14:44:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	30 Sep 2020 14:44:03
Data point term sent to Coder	System	30 Sep 2020 14:42:35
User entered 'obstructive sleep apnea'	Karen Mylerberg (b) (4)	30 Sep 2020 14:42:25

US3112030

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'UN Jan 1993'	Karen Mylerberg (b) (4)	30 Sep 2020 14:42:25

US3112030

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	Karen Mylerberg (b) (4)	30 Sep 2020 14:42:25

US3112030

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:11:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	30 Sep 2020 14:42:25

US3112030

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered empty.	Karen Mylerberg (b) (4)	30 Sep 2020 14:42:25

US3112030

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:11:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	Karen Mylerberg (b) (4)	30 Sep 2020 14:42:25

US3112030

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered 'Jan 1993'	System	30 Sep 2020 14:42:25

US3112030

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered '1993'	System	30 Sep 2020 14:42:25

US3112030

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered empty.	System	30 Sep 2020 14:42:25

US3112030

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered empty.	System	30 Sep 2020 14:42:25

US3112030

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:11:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 14:44:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 14:44:50
Data point term sent to Coder	System	30 Sep 2020 14:43:35
User entered 'moderate asthma'	Karen Mylerberg (b) (4)	30 Sep 2020 14:42:47

US3112030

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'UN Apr 2010'	Karen Mylerberg (b) (4)	30 Sep 2020 14:42:47

US3112030

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	Karen Mylerberg (b) (4)	30 Sep 2020 14:42:47

US3112030

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:11:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	30 Sep 2020 14:42:47

US3112030

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered empty.	Karen Mylerberg (b) (4)	30 Sep 2020 14:42:47

US3112030

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:11:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	Karen Mylerberg (b) (4)	30 Sep 2020 14:42:47

US3112030

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered 'Apr 2010'	System	30 Sep 2020 14:42:47

US3112030

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered '2010'	System	30 Sep 2020 14:42:47

US3112030

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered empty.	System	30 Sep 2020 14:42:47

US3112030

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered empty.	System	30 Sep 2020 14:42:47

US3112030

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:11:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 14:44:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 14:44:49
Data point term sent to Coder	System	30 Sep 2020 14:43:40
User entered 'hyperlipidemia'	Karen Mylerberg (b) (4)	30 Sep 2020 14:43:13

US3112030

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'UN Jan 2019'	Karen Mylerberg (b) (4)	30 Sep 2020 14:43:13

US3112030

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	Karen Mylerberg (b) (4)	30 Sep 2020 14:43:13

US3112030

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:11:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	30 Sep 2020 14:43:13

US3112030

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered empty.	Karen Mylerberg (b) (4)	30 Sep 2020 14:43:13

US3112030

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:11:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	Karen Mylerberg (b) (4)	30 Sep 2020 14:43:13

US3112030

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered 'Jan 2019'	System	30 Sep 2020 14:43:13

US3112030

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered '2019'	System	30 Sep 2020 14:43:13

US3112030

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered empty.	System	30 Sep 2020 14:43:13

US3112030

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered empty.	System	30 Sep 2020 14:43:13

US3112030

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:11:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 14:46:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 14:46:47
Data point term sent to Coder	System	30 Sep 2020 14:45:46
User entered 'Gastroesophageal reflux disease'	Karen Mylerberg (b) (4)	30 Sep 2020 14:45:03

US3112030

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'UN UNK 2012'	Karen Mylerberg (b) (4)	30 Sep 2020 14:45:03

US3112030

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	Karen Mylerberg (b) (4)	30 Sep 2020 14:45:03

US3112030

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:11:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	30 Sep 2020 14:45:03

US3112030

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered empty.	Karen Mylerberg (b) (4)	30 Sep 2020 14:45:03

US3112030

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:11:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	Karen Mylerberg (b) (4)	30 Sep 2020 14:45:03

US3112030

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered 'Jan 2012'	System	30 Sep 2020 14:45:03

US3112030

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered '2012'	System	30 Sep 2020 14:45:03

US3112030

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered empty.	System	30 Sep 2020 14:45:03

US3112030

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered empty.	System	30 Sep 2020 14:45:03

US3112030

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:11:47

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Peripheral sensory neuropathy, LLT: Peripheral sensory neuropathy - version MedDRA\23.0.	Coder Import (b) (4)	25 Nov 2020 00:00:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	25 Nov 2020 00:00:58
Data point term sent to Coder	System	24 Nov 2020 22:55:32
Coding entries removed.	Matthew Musikanth (b) (4)	24 Nov 2020 22:54:48
User entered 'BILATERAL feet PERIPHERAL SENSORY NEUROPATHY' reason for change:	Matthew Musikanth (b) (4)	24 Nov 2020 22:54:48
Data Entry Error		
Query 'Per DM CLR: Please specify the location of BILATERAL PERIPHERAL SENSORY NEUROPATHY (e.g. arms, legs, etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' canceled (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 13:22:20
User opened query 'Per DM CLR: Please specify the location of BILATERAL PERIPHERAL SENSORY NEUROPATHY (e.g. arms, legs, etc). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 13:05:56
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Peripheral sensory neuropathy, LLT: Peripheral sensory neuropathy - version MedDRA\23.0.	Coder Import (b) (4)	30 Sep 2020 15:17:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	30 Sep 2020 15:17:54
Data point term sent to Coder	System	30 Sep 2020 14:45:50
User entered 'bilateral peripheral sensory neuropathy'	Karen Mylerberg (b) (4)	30 Sep 2020 14:45:36

US3112030

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'UN Mar 2010'	Karen Mylerberg (b) (4)	30 Sep 2020 14:45:36

US3112030

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	Karen Mylerberg (b) (4)	30 Sep 2020 14:45:36

US3112030

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:11:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	30 Sep 2020 14:45:36

US3112030

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered empty.	Karen Mylerberg (b) (4)	30 Sep 2020 14:45:36

US3112030

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:11:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	Karen Mylerberg (b) (4)	30 Sep 2020 14:45:36

US3112030

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered 'Mar 2010'	System	30 Sep 2020 14:45:36

US3112030

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered '2010'	System	30 Sep 2020 14:45:36

US3112030

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered empty.	System	30 Sep 2020 14:45:36

US3112030

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered empty.	System	30 Sep 2020 14:45:36

US3112030

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:11:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User coded data point as SOC: Reproductive system and breast disorders, HLG: Sexual function and fertility disorders, HLT: Erection and ejaculation conditions and disorders, PT: Erectile dysfunction, LLT: Erectile dysfunction - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 14:47:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 14:47:51
Data point term sent to Coder	System	30 Sep 2020 14:46:51
User entered 'erectile dysfunction'	Karen Mylerberg (b) (4)	30 Sep 2020 14:46:02

US3112030

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'UN Jul 2004'	Karen Mylerberg (b) (4)	30 Sep 2020 14:46:02

US3112030

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	Karen Mylerberg (b) (4)	30 Sep 2020 14:46:02

US3112030

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:11:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	30 Sep 2020 14:46:02

US3112030

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:11:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered empty.	Karen Mylerberg (b) (4)	30 Sep 2020 14:46:02

US3112030

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:11:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	Karen Mylerberg (b) (4)	30 Sep 2020 14:46:02

US3112030

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered 'Jul 2004'	System	30 Sep 2020 14:46:02

US3112030

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered '2004'	System	30 Sep 2020 14:46:02

US3112030

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered empty.	System	30 Sep 2020 14:46:02

US3112030

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered empty.	System	30 Sep 2020 14:46:02

US3112030

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:11:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hyperplasia - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 14:47:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 14:47:51
Data point term sent to Coder	System	30 Sep 2020 14:46:51
User entered 'Benign prostatic hyperplasia'	Karen Mylerberg (b) (4)	30 Sep 2020 14:46:38

US3112030

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'UN Jan 2009'	Karen Mylerberg (b) (4)	30 Sep 2020 14:46:38

US3112030

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	Karen Mylerberg (b) (4)	30 Sep 2020 14:46:38

US3112030

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:11:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User closed query 'Per CDM: Per your response "Condition is ongoing", please confirm is a stop date should be as the subject had a procedure (Transurethral Resection of the Prostate) directly related to this condition.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 03:52:58
Query 'Per CDM: Per your response "Condition is ongoing", please confirm is a stop date should be as the subject had a procedure (Transurethral Resection of the Prostate) directly related to this condition.' answered with 'updated' (Site from DM).	Matthew Musikanth (b) (4)	24 Nov 2020 22:54:24
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	24 Nov 2020 22:54:18
User opened query 'Per CDM: Per your response "Condition is ongoing", please confirm is a stop date should be as the subject had a procedure (Transurethral Resection of the Prostate) directly related to this condition.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 19:48:15
User closed query 'Per DM CLR: Please verify if stop date should be added as MH #14 TRANSURETHRAL RESECTION OF THE PROSTATE is recorded on UN JUL 2012. Update the eCRF as appropriate. Otherwise, provide explanation.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 19:48:15
Query 'Per DM CLR: Please verify if stop date should be added as MH #14 TRANSURETHRAL RESECTION OF THE PROSTATE is recorded on UN JUL 2012. Update the eCRF as appropriate. Otherwise, provide explanation.' answered with 'condition is ong' (Site from DM).	Natalie Moy (b) (4) (b) (4)	26 Oct 2020 16:54:33
User opened query 'Per DM CLR: Please verify if stop date should be added as MH #14 TRANSURETHRAL RESECTION OF THE PROSTATE is recorded on UN JUL 2012. Update the eCRF as appropriate. Otherwise, provide explanation.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 13:06:36
User entered 'Yes (Y)'	Karen Mylerberg (b) (4) (b) (4)	30 Sep 2020 14:46:38

US3112030

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:11:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'un Jul 2012' reason for change: Data Entry Error	(b) (4)	24 Nov 2020 22:54:18
User entered empty.	Matthew Musikanth (b) (4)	30 Sep 2020 14:46:38
	Karen Mylerberg (b) (4)	
	(b) (4)	

US3112030

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:11:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	Karen Mylerberg (b) (4)	30 Sep 2020 14:46:38

US3112030

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered 'Jan 2009'	System	30 Sep 2020 14:46:38

US3112030

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered '2009'	System	30 Sep 2020 14:46:38

US3112030

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered 'Jul 2012'	System	24 Nov 2020 22:54:18
User entered empty.	System	30 Sep 2020 14:46:38

US3112030

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered '2012'	System	24 Nov 2020 22:54:18
User entered empty.	System	30 Sep 2020 14:46:38

US3112030

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:11:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User coded data point as SOC: Renal and urinary disorders, HLGT: Bladder and bladder neck disorders (excl calculi), HLT: Myoneurogenic bladder disorders, PT: Hypertonic bladder, LLT: Overactive bladder - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 14:48:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 14:48:53
Data point term sent to Coder	System	30 Sep 2020 14:47:52
User entered 'overactive bladder'	Karen Mylerberg (b) (4)	30 Sep 2020 14:46:59

US3112030

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'UN Dec 2018'	Karen Mylerberg (b) (4)	30 Sep 2020 14:46:59

US3112030

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	Karen Mylerberg (b) (4)	30 Sep 2020 14:46:59

US3112030

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:11:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	30 Sep 2020 14:46:59

US3112030

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered empty.	Karen Mylerberg (b) (4)	30 Sep 2020 14:46:59

US3112030

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:11:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	Karen Mylerberg (b) (4)	30 Sep 2020 14:46:59

US3112030

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered 'Dec 2018'	System	30 Sep 2020 14:46:59

US3112030

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered '2018'	System	30 Sep 2020 14:46:59

US3112030

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered empty.	System	30 Sep 2020 14:46:59

US3112030

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered empty.	System	30 Sep 2020 14:46:59

US3112030

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:11:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Spine and neck deformities, PT: Scoliosis, LLT: Thoracogenic scoliosis - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 16:17:04
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 16:17:04
Data point term sent to Coder	System	30 Sep 2020 14:47:53
User entered 'scoliosis t-spine'	Karen Mylerberg (b) (4)	30 Sep 2020 14:47:23

US3112030

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'UN Apr 1988'	Karen Mylerberg (b) (4)	30 Sep 2020 14:47:23

US3112030

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	Karen Mylerberg (b) (4)	30 Sep 2020 14:47:23

US3112030

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:11:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	30 Sep 2020 14:47:23

US3112030

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:11:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered empty.	Karen Mylerberg (b) (4)	30 Sep 2020 14:47:23

US3112030

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:11:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	Karen Mylerberg (b) (4)	30 Sep 2020 14:47:23

US3112030

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered 'Apr 1988'	System	30 Sep 2020 14:47:23

US3112030

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered '1988'	System	30 Sep 2020 14:47:23

US3112030

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered empty.	System	30 Sep 2020 14:47:23

US3112030

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered empty.	System	30 Sep 2020 14:47:23

US3112030

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:11:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis knees - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 14:48:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 14:48:54
Data point term sent to Coder	System	30 Sep 2020 14:47:53
User entered 'bilateral knee osteoarthritis'	Karen Mylerberg (b) (4)	30 Sep 2020 14:47:49

US3112030

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'UN Sep 1987'	Karen Mylerberg (b) (4)	30 Sep 2020 14:47:49

US3112030

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	Karen Mylerberg (b) (4)	30 Sep 2020 14:47:49

US3112030

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:11:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	30 Sep 2020 14:47:49

US3112030

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:11:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered empty.	Karen Mylerberg (b) (4)	30 Sep 2020 14:47:49

US3112030

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:11:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	Karen Mylerberg (b) (4)	30 Sep 2020 14:47:49

US3112030

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered 'Sep 1987'	System	30 Sep 2020 14:47:49

US3112030

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered '1987'	System	30 Sep 2020 14:47:49

US3112030

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered empty.	System	30 Sep 2020 14:47:49

US3112030

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered empty.	System	30 Sep 2020 14:47:49

US3112030

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:11:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
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)	30 Sep 2020 14:49:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 14:49:50
Data point term sent to Coder	System	30 Sep 2020 14:48:54
User entered 'Type II Diabetes'	Karen Mylerberg (b) (4)	30 Sep 2020 14:48:12

US3112030

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'UN Apr 1988'	Karen Mylerberg (b) (4)	30 Sep 2020 14:48:12

US3112030

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	Karen Mylerberg (b) (4)	30 Sep 2020 14:48:12

US3112030

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:11:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	30 Sep 2020 14:48:12

US3112030

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered empty.	Karen Mylerberg (b) (4)	30 Sep 2020 14:48:12

US3112030

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:11:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	Karen Mylerberg (b) (4)	30 Sep 2020 14:48:12

US3112030

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered 'Apr 1988'	System	30 Sep 2020 14:48:12

US3112030

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered '1988'	System	30 Sep 2020 14:48:12

US3112030

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered empty.	System	30 Sep 2020 14:48:12

US3112030

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered empty.	System	30 Sep 2020 14:48:12

US3112030

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:11:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc protrusion, LLT: Cervical disc herniation - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 15:21:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 15:21:56
Data point term sent to Coder	System	30 Sep 2020 14:48:54
User entered 'herniated C5 and C6'	Karen Mylerberg (b) (4)	30 Sep 2020 14:48:40

US3112030

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'UN Jun 2010'	Karen Mylerberg (b) (4)	30 Sep 2020 14:48:40

US3112030

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	Karen Mylerberg (b) (4)	30 Sep 2020 14:48:40

US3112030

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:11:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	30 Sep 2020 14:48:40

US3112030

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered empty.	Karen Mylerberg (b) (4)	30 Sep 2020 14:48:40

US3112030

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:11:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	Karen Mylerberg (b) (4)	30 Sep 2020 14:48:40

US3112030

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered 'Jun 2010'	System	30 Sep 2020 14:48:40

US3112030

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered '2010'	System	30 Sep 2020 14:48:40

US3112030

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered empty.	System	30 Sep 2020 14:48:40

US3112030

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered empty.	System	30 Sep 2020 14:48:40

US3112030

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:11:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Prostatic therapeutic procedures, PT: Transurethral prostatectomy, LLT: Prostate transurethral resection - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 14:50:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 14:50:51
Data point term sent to Coder	System	30 Sep 2020 14:49:55
User entered 'Transurethral resection of the prostate'	Karen Mylerberg (b) (4)	30 Sep 2020 14:49:26

US3112030

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'un Jul 2012'	Karen Mylerberg (b) (4)	30 Sep 2020 14:49:26

US3112030

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	Karen Mylerberg (b) (4)	30 Sep 2020 14:49:26

US3112030

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:11:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Karen Mylerberg (b) (4)	30 Sep 2020 14:50:25
User entered 'Yes (Y)'	(b) (4)	
	Karen Mylerberg (b) (4)	30 Sep 2020 14:49:26
	(b) (4)	

US3112030

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:11:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'un Jul 2012' reason for change: Data Entry Error	(b) (4)	
	Karen Mylerberg (b) (4)	30 Sep 2020 14:50:25
User entered empty.	(b) (4)	
	Karen Mylerberg (b) (4)	30 Sep 2020 14:49:26
	(b) (4)	

US3112030

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:11:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	Karen Mylerberg (b) (4)	30 Sep 2020 14:49:26

US3112030

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered 'Jul 2012'	System	30 Sep 2020 14:49:26

US3112030

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered '2012'	System	30 Sep 2020 14:49:26

US3112030

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered 'Jul 2012'	System	30 Sep 2020 14:50:25
User entered empty.	System	30 Sep 2020 14:49:26

US3112030

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered '2012'	System	30 Sep 2020 14:50:25
User entered empty.	System	30 Sep 2020 14:49:26

US3112030

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:11:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
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)	30 Sep 2020 14:51:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 14:51:54
Data point term sent to Coder	System	30 Sep 2020 14:50:57
User entered 'left total knee replacement'	Karen Mylerberg (b) (4)	30 Sep 2020 14:50:04

US3112030

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '31 Jul 2019'	Karen Mylerberg (b) (4)	30 Sep 2020 14:50:04

US3112030

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	Karen Mylerberg (b) (4)	30 Sep 2020 14:50:04

US3112030

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:11:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'No (N)'	Karen Mylerberg (b) (4)	30 Sep 2020 14:50:04

US3112030

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '31 Jul 2019'	Karen Mylerberg (b) (4)	30 Sep 2020 14:50:04

US3112030

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:11:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	Karen Mylerberg (b) (4)	30 Sep 2020 14:50:04

US3112030

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered 'Jul 2019'	System	30 Sep 2020 14:50:04

US3112030

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered '2019'	System	30 Sep 2020 14:50:04

US3112030

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered 'Jul 2019'	System	30 Sep 2020 14:50:04

US3112030

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered '2019'	System	30 Sep 2020 14:50:04

US3112030

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:11:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User coded data point as SOC: Eye disorders, HLGT: Eye disorders NEC, HLT: Lacrimation disorders, PT: Dry eye, LLT: Dry eyes - version MedDRA\\23.0.	Coder Import (b) (4)	04 Feb 2021 17:29:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Feb 2021 17:29:48
Data point term sent to Coder	System	04 Feb 2021 17:28:37
User entered 'Dry eyes'	Matthew Musikanth (b) (4)	04 Feb 2021 17:28:18

US3112030

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'un UNK 2018'	(b) (4) Matthew Musikanth (b) (4)	04 Feb 2021 17:28:18

US3112030

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	04 Feb 2021 17:28:18

US3112030

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:11:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:28:18

US3112030

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:11:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered empty.	(b) (4) Matthew Musikanth	04 Feb 2021 17:28:18
	(b) (4)	

US3112030

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:11:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	04 Feb 2021 17:28:18

US3112030

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered 'Jan 2018'	System	04 Feb 2021 17:28:18

US3112030

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered '2018'	System	04 Feb 2021 17:28:18

US3112030

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered empty.	System	04 Feb 2021 17:28:18

US3112030

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered empty.	System	04 Feb 2021 17:28:18

US3112030

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:11:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Hay fever - version MedDRA\\23.0.	Coder Import (b) (4)	04 Feb 2021 17:30:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Feb 2021 17:30:47
Data point term sent to Coder	System	04 Feb 2021 17:29:39
User entered 'Hay fever'	Matthew Musikanth (b) (4)	04 Feb 2021 17:28:52

US3112030

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'un UNK 2009'	(b) (4) Matthew Musikanth (b) (4)	04 Feb 2021 17:28:52

US3112030

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	04 Feb 2021 17:28:52

US3112030

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:11:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:28:52

US3112030

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:11:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered empty.	(b) (4) Matthew Musikanth	04 Feb 2021 17:28:52
	(b) (4)	

US3112030

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:11:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	Matthew Musikanth (b) (4)	04 Feb 2021 17:28:52

US3112030

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered 'Jan 2009'	System	04 Feb 2021 17:28:52

US3112030

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered '2009'	System	04 Feb 2021 17:28:52

US3112030

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered empty.	System	04 Feb 2021 17:28:52

US3112030

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered empty.	System	04 Feb 2021 17:28:52

US3112030

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:11:47

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation - version MedDRA\\23.0.	Coder Import (b) (4)	04 Feb 2021 17:30:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Feb 2021 17:30:48
Data point term sent to Coder	System	04 Feb 2021 17:29:39
User entered 'constipation'	Matthew Musikanth (b) (4)	04 Feb 2021 17:29:15

US3112030

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'un UNK 2009'	(b) (4) Matthew Musikanth (b) (4)	04 Feb 2021 17:29:15

US3112030

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	04 Feb 2021 17:29:15

US3112030

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:11:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth (b) (4)	04 Feb 2021 17:29:15

US3112030

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered empty.	(b) (4) Matthew Musikanth (b) (4)	04 Feb 2021 17:29:15

US3112030

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:11:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	04 Feb 2021 17:29:15

US3112030

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered 'Jan 2009'	System	04 Feb 2021 17:29:15

US3112030

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered '2009'	System	04 Feb 2021 17:29:15

US3112030

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered empty.	System	04 Feb 2021 17:29:15

US3112030

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered empty.	System	04 Feb 2021 17:29:15

US3112030

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:11:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
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)	04 Feb 2021 17:30:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Feb 2021 17:30:48
Data point term sent to Coder	System	04 Feb 2021 17:29:39
User entered 'Hypertension'	Matthew Musikanth (b) (4)	04 Feb 2021 17:29:34

US3112030

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'un UNK 2016'	Matthew Musikanth (b) (4)	04 Feb 2021 17:29:34

US3112030

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	04 Feb 2021 17:29:34

US3112030

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:11:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:29:34

US3112030

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered empty.	(b) (4) Matthew Musikanth (b) (4)	04 Feb 2021 17:29:34

US3112030

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:11:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	04 Feb 2021 17:29:34

US3112030

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered 'Jan 2016'	System	04 Feb 2021 17:29:34

US3112030

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered '2016'	System	04 Feb 2021 17:29:34

US3112030

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered empty.	System	04 Feb 2021 17:29:34

US3112030

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered empty.	System	04 Feb 2021 17:29:34

US3112030

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:11:47

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Knee pain - version MedDRA\\23.0.	Coder Import (b) (4)	04 Feb 2021 17:31:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Feb 2021 17:31:47
Data point term sent to Coder	System	04 Feb 2021 17:30:41
User entered 'Bilateral Knee Pain'	Matthew Musikanth (b) (4)	04 Feb 2021 17:30:23

US3112030

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'un UNK 2010'	Matthew Musikanth (b) (4)	04 Feb 2021 17:30:23

US3112030

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	04 Feb 2021 17:30:23

US3112030

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:11:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:30:23

US3112030

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered empty.	(b) (4) Matthew Musikanth	04 Feb 2021 17:30:23
	(b) (4)	

US3112030

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:11:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	04 Feb 2021 17:30:23

US3112030

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered 'Jan 2010'	System	04 Feb 2021 17:30:23

US3112030

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered '2010'	System	04 Feb 2021 17:30:23

US3112030

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered empty.	System	04 Feb 2021 17:30:23

US3112030

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered empty.	System	04 Feb 2021 17:30:23

US3112030

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:11:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Rashes, eruptions and exanthems NEC, PT: Rash, LLT: Localized rash - version MedDRA\\23.0.	Coder Import (b) (4)	04 Feb 2021 22:47:28
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	04 Feb 2021 22:47:28
Data point term sent to Coder	System	04 Feb 2021 17:31:42
User entered 'Intermittent Skin Rash L Shoulder'	Matthew Musikanth (b) (4)	04 Feb 2021 17:30:48

US3112030

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'un Feb 2020'	(b) (4) Matthew Musikanth (b) (4)	04 Feb 2021 17:30:48

US3112030

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	04 Feb 2021 17:30:48

US3112030

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:11:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth (b) (4)	04 Feb 2021 17:30:48

US3112030

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered empty.	(b) (4) Matthew Musikanth	04 Feb 2021 17:30:48
	(b) (4)	

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Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:11:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	(b) (4) Matthew Musikanth (b) (4)	04 Feb 2021 17:30:48

US3112030

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered 'Feb 2020'	System	04 Feb 2021 17:30:48

US3112030

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered '2020'	System	04 Feb 2021 17:30:48

US3112030

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered empty.	System	04 Feb 2021 17:30:48

US3112030

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered empty.	System	04 Feb 2021 17:30:48

US3112030

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:11:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:27
User coded data point as SOC: Gastrointestinal disorders, HLGT: Dental and gingival conditions, HLT: Dental and periodontal infections and inflammations, PT: Dental caries, LLT: Tooth cavity - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 16:31:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 16:31:57
Data point term sent to Coder	System	15 Mar 2021 16:31:14
User closed query 'For coding purposes, please provide more information for term CAVITY. Is Tooth Cavity meant or something else.' (Site from System).	System	15 Mar 2021 16:31:01
Query 'For coding purposes, please provide more information for term CAVITY. Is Tooth Cavity meant or something else.' answered with 'condition term has been updated ' (Site from System).	Brenda Grande (b) (4)	15 Mar 2021 16:31:01
Coding entries removed.	Brenda Grande (b) (4)	15 Mar 2021 16:30:17
Signature has been broken.	Brenda Grande (b) (4)	15 Mar 2021 16:30:17
User entered 'TOoth CAVITY' reason for change: Data Entry Error	Brenda Grande (b) (4)	15 Mar 2021 16:30:17
User opened query 'For coding purposes, please provide more information for term CAVITY. Is Tooth Cavity meant or something else.' (Site from System).	Coder Import (b) (4)	12 Mar 2021 20:02:49
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:40:25
User coded data point as SOC: Gastrointestinal disorders, HLGT: Dental and gingival conditions, HLT: Dental and periodontal infections and inflammations, PT: Dental caries, LLT: Tooth cavity - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 18:48:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 18:48:52

US3112030

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:11:47

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Dental and gingival conditions, HLT: Dental and periodontal infections and inflammations, PT: Dental caries, LLT: Tooth cavity - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 18:33:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 18:33:53
User coded data point as SOC: Gastrointestinal disorders, HLGT: Dental and gingival conditions, HLT: Dental and periodontal infections and inflammations, PT: Dental caries, LLT: Tooth cavity - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 18:18:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 18:18:54
Data point term sent to Coder	System	26 Feb 2021 18:18:17
User entered 'cavity'	Brenda Grande (b) (4)	26 Feb 2021 18:17:30

US3112030

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:40:25
User entered empty.	Brenda Grande (b) (4)	26 Feb 2021 18:17:30

US3112030

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:40:25
User entered 'I'	Brenda Grande (b) (4)	26 Feb 2021 18:17:30

US3112030

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:11:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:40:25
User entered 'No (N)'	Brenda Grande (b) (4)	26 Feb 2021 18:17:30

US3112030

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:11:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:40:25
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	26 Feb 2021 18:17:38
User entered '11 Dec 2020' reason for change: Data Entry Error	Brenda Grande (b) (4)	26 Feb 2021 18:17:38
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	26 Feb 2021 18:17:30
User entered '11 Dec 2021'	Brenda Grande (b) (4)	26 Feb 2021 18:17:30

US3112030

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:11:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:40:25
User entered '0'	Brenda Grande (b) (4)	26 Feb 2021 18:17:30

US3112030

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered empty.	System	26 Feb 2021 18:17:30

US3112030

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered empty.	System	26 Feb 2021 18:17:30

US3112030

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered 'Dec 2020'	System	26 Feb 2021 18:17:38
User entered 'Dec 2021'	System	26 Feb 2021 18:17:30

US3112030

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered '2020'	System	26 Feb 2021 18:17:38
User entered '2021'	System	26 Feb 2021 18:17:30

US3112030

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	01 Aug 2020 00:51:24

US3112030

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '30 Jul 2020'	Karen Mylerberg (b) (4)	01 Aug 2020 00:51:24

US3112030

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '11:56'	Karen Mylerberg (b) (4)	01 Aug 2020 00:51:24

US3112030

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered '30 Jul 2020 11:56'	System	01 Aug 2020 00:51:24

US3112030

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '163' cm	(b) (4) Karen Mylerberg (b) (4)	01 Aug 2020 00:51:24
DataPoint set to visible.	(b) (4) System	30 Jul 2020 20:40:33

US3112030

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '83.2' kg	Karen Mylerberg (b) (4)	01 Aug 2020 00:51:24
DataPoint set to visible.	System	30 Jul 2020 20:40:33

US3112030

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
Amendment Manager: User entered '31.31469'	System	16 Sep 2020 23:39:06
User entered '31.3'	System	01 Aug 2020 00:51:24
DataPoint set to visible.	System	30 Jul 2020 20:40:33

US3112030

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered 'kg/m2'	System	01 Aug 2020 00:51:24
DataPoint set to visible.	System	30 Jul 2020 20:40:33

US3112030

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 14:45:06
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' answered with 'updated' (Site from DM).	Karen Mylerberg (b) (4)	01 Sep 2020 19:03:40
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	01 Sep 2020 19:03:34
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	20 Aug 2020 16:28:53
User entered '98.3' F	Karen Mylerberg (b) (4)	01 Aug 2020 00:51:24

US3112030

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered empty; reason for change Data Entry Error	(b) (4)	
	Karen Mylerberg (b) (4)	01 Sep 2020 19:03:34
User entered 'Oral (Oral)'	(b) (4)	
	Karen Mylerberg (b) (4)	01 Aug 2020 00:51:24
	(b) (4)	

US3112030

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered empty.	Karen Mylerberg (b) (4)	01 Aug 2020 00:51:24

US3112030

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	01 Sep 2020 19:03:34
User entered '78'	Karen Mylerberg (b) (4)	01 Aug 2020 00:51:24

US3112030

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered 'bpm'	System	01 Aug 2020 00:51:24

US3112030

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	01 Sep 2020 19:03:34
User entered '17'	Karen Mylerberg (b) (4)	01 Aug 2020 00:51:24

US3112030

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered 'breaths/min'	System	01 Aug 2020 00:51:24

US3112030

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	01 Sep 2020 19:03:34
User entered '118'	Karen Mylerberg (b) (4)	01 Aug 2020 00:51:24

US3112030

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered 'mmHg'	System	01 Aug 2020 00:51:24

US3112030

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	01 Sep 2020 19:03:34
User entered '074'	Karen Mylerberg (b) (4)	01 Aug 2020 00:51:24

US3112030

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User entered 'mmHg'	System	01 Aug 2020 00:51:24

US3112030

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33

US3112030

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33

US3112030

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:11:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	01 Aug 2020 00:51:36

US3112030

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:11:47

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	07 Sep 2020 07:43:21
Comment added 'Date of screening visit was 30 Jul 2020. Value entered is correct'.	Karen Mylerberg (b) (4)	01 Sep 2020 19:07:50
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	27 Aug 2020 19:29:29
User entered '30 Jul 2020'	Karen Mylerberg (b) (4)	01 Aug 2020 00:51:36

US3112030

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:47

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 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'No (N)'	(b) (4) Karen Mylerberg (b) (4)	01 Aug 2020 00:52:28

US3112030

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:47

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 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'No (N)'	(b) (4) Karen Mylerberg (b) (4)	01 Aug 2020 00:52:28

US3112030

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:47

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 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'No (N)'	Karen Mylerberg (b) (4)	01 Aug 2020 00:52:28

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:47

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 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'No (N)'	Karen Mylerberg (b) (4)	01 Aug 2020 00:52:28

US3112030

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:47

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 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'No (N)'	Karen Mylerberg (b) (4)	01 Aug 2020 00:52:28

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:47

[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 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'No (N)'	Karen Mylerberg (b) (4)	01 Aug 2020 00:52:28

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:47

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 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'No (N)'	Karen Mylerberg (b) (4)	01 Aug 2020 00:52:28

US3112030

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:47

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 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'No (N)'	Karen Mylerberg (b) (4)	01 Aug 2020 00:52:28

US3112030

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:47

[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 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'No (N)'	(b) (4) Karen Mylerberg (b) (4)	01 Aug 2020 00:52:28

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:47

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 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'No (N)'	Karen Mylerberg (b) (4)	01 Aug 2020 00:52:28

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:47

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 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'No (N)'	Karen Mylerberg (b) (4)	01 Aug 2020 00:52:28

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:47

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'No (N)'	Karen Mylerberg (b) (4)	01 Aug 2020 00:52:28

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:47

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered empty.	Karen Mylerberg (b) (4)	01 Aug 2020 00:52:28

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:47

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	Karen Mylerberg (b) (4)	01 Aug 2020 00:52:28

US3112030

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:47

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	Karen Mylerberg (b) (4)	01 Aug 2020 00:52:28

US3112030

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:47

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 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	Karen Mylerberg (b) (4)	01 Aug 2020 00:52:28

US3112030

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:47

[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 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	Karen Mylerberg (b) (4)	01 Aug 2020 00:52:28

US3112030

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:47

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 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	Karen Mylerberg (b) (4)	01 Aug 2020 00:52:28

US3112030

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:47

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered '0'	Karen Mylerberg (b) (4)	01 Aug 2020 00:52:28

US3112030

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:47

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'I'	Karen Mylerberg (b) (4)	01 Aug 2020 00:52:28

US3112030

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:11:47

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:13:33
User signature succeeded.	Laurie Han-Conrad (b) (4)	19 Feb 2021 16:37:40
User entered 'Resident in a community with ongoing person to person transmission'	(b) (4) Karen Mylerberg (b) (4)	01 Aug 2020 00:52:28

US3112030

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:11:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	30 Jul 2020 20:39:54

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '30 Jul 2020'	Karen Mylerberg (b) (4)	30 Jul 2020 20:39:54

US3112030

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered 'Clinic (Clinic)'	Karen Mylerberg (b) (4)	30 Jul 2020 20:39:54

US3112030

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:11:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User entered 'VISIT1'	System	30 Jul 2020 20:39:54

US3112030

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '30 JUL 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	30 Jul 2020 19:54:12

US3112030

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:11:47

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 01:24:19
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:24:19
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	30 Jul 2020 19:54:12
User entered '184249' (non-conformant).	RWS_ENDPOINT (b) (4)	30 Jul 2020 19:54:12
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:11:47

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	30 Jul 2020 19:54:12

US3112030

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:11:47

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)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered 'No (N)'	Karen Mylerberg (b) (4)	01 Aug 2020 00:47:15

US3112030

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:11:47

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)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered 'No (N)'	Karen Mylerberg (b) (4)	01 Aug 2020 00:47:15

US3112030

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:11:47

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered 'No (N)'	Karen Mylerberg (b) (4)	01 Aug 2020 00:47:15

US3112030

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:11:47

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	01 Aug 2020 00:47:15

US3112030

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:11:47

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered 'No (N)'	Karen Mylerberg (b) (4)	01 Aug 2020 00:47:15

US3112030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:11:47

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered missing code ND - Not Done.	Karen Mylerberg (b) (4)	01 Aug 2020 00:54:41

US3112030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:11:47

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered missing code ND - Not Done.	Karen Mylerberg (b) (4)	01 Aug 2020 00:54:41

US3112030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:11:47

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered missing code ND - Not Done.	Karen Mylerberg (b) (4)	01 Aug 2020 00:54:41

US3112030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:11:47

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered missing code ND - Not Done.	Karen Mylerberg (b) (4)	01 Aug 2020 00:54:41

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User accepted default value 'Pre-Dose (PREDOSE)'	Karen Mylerberg (b) (4)	01 Aug 2020 00:54:41

US3112030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	01 Aug 2020 00:54:41

US3112030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '30 Jul 2020'	Karen Mylerberg (b) (4)	01 Aug 2020 00:54:41

US3112030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '11:56'	Karen Mylerberg (b) (4)	01 Aug 2020 00:54:41

US3112030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User entered '30 Jul 2020 11:56'	System	01 Aug 2020 00:54:41

US3112030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '98.3' F	Karen Mylerberg (b) (4)	01 Aug 2020 00:54:41

US3112030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered 'Oral (Oral)'	Karen Mylerberg (b) (4)	01 Aug 2020 00:54:41

US3112030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered empty.	Karen Mylerberg (b) (4)	01 Aug 2020 00:54:41

US3112030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '78'	Karen Mylerberg (b) (4)	01 Aug 2020 00:54:41

US3112030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User entered 'bpm'	System	01 Aug 2020 00:54:41

US3112030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '17'	Karen Mylerberg (b) (4)	01 Aug 2020 00:54:41

US3112030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User entered 'breaths/min'	System	01 Aug 2020 00:54:41

US3112030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '124'	Karen Mylerberg (b) (4)	01 Aug 2020 00:54:41

US3112030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User entered 'mmHg'	System	01 Aug 2020 00:54:41

US3112030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '072'	Karen Mylerberg (b) (4)	01 Aug 2020 00:54:41

US3112030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User entered 'mmHg'	System	01 Aug 2020 00:54:41

US3112030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:11:47

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered missing code ND - Not Done.	Karen Mylerberg (b) (4)	01 Aug 2020 00:54:41

US3112030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:11:47

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered missing code ND - Not Done.	Karen Mylerberg (b) (4)	01 Aug 2020 00:54:41

US3112030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User accepted default value 'Post-Dose (POSTDOSE)'	Karen Mylerberg (b) (4)	01 Aug 2020 00:54:41

US3112030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	01 Aug 2020 00:54:41

US3112030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '30 Jul 2020'	Karen Mylerberg (b) (4)	01 Aug 2020 00:54:41

US3112030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	05 Aug 2020 20:07:49
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Vitals obtained at least 30 minutes post dosing per protocol' (Site from System).	Karen Mylerberg (b) (4) (b) (4)	02 Aug 2020 23:31:44
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		01 Aug 2020 00:54:41
User entered '14:00'	Karen Mylerberg (b) (4) (b) (4)	01 Aug 2020 00:54:41

US3112030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User entered '30 Jul 2020 14:00'	System	01 Aug 2020 00:54:41

US3112030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '98.0' F	Karen Mylerberg (b) (4)	01 Aug 2020 00:54:41

US3112030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered 'Oral (Oral)'	Karen Mylerberg (b) (4)	01 Aug 2020 00:54:41

US3112030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered empty.	Karen Mylerberg (b) (4)	01 Aug 2020 00:54:41

US3112030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '76'	Karen Mylerberg (b) (4)	01 Aug 2020 00:54:41

US3112030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User entered 'bpm'	System	01 Aug 2020 00:54:41

US3112030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '16'	Karen Mylerberg (b) (4)	01 Aug 2020 00:54:41

US3112030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User entered 'breaths/min'	System	01 Aug 2020 00:54:41

US3112030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '118'	Karen Mylerberg (b) (4)	01 Aug 2020 00:54:41

US3112030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User entered 'mmHg'	System	01 Aug 2020 00:54:41

US3112030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '076'	Karen Mylerberg (b) (4)	01 Aug 2020 00:54:41

US3112030

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User entered 'mmHg'	System	01 Aug 2020 00:54:41

US3112030

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:11:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered 'No (N)'	Karen Mylerberg (b) (4)	01 Aug 2020 00:55:15

US3112030

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:11:47

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered empty.	Karen Mylerberg (b) (4)	01 Aug 2020 00:55:15

US3112030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:11:47

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	30 Jul 2020 20:41:05

US3112030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:11:47

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered empty.	Karen Mylerberg (b) (4)	30 Jul 2020 20:41:05

US3112030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:11:47

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)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered empty.	Karen Mylerberg (b) (4)	30 Jul 2020 20:41:05

US3112030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:11:47

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User entered 'MRNA-1273 OR PLACEBO'	System	30 Jul 2020 20:41:05

US3112030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:11:47

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '30 Jul 2020'	Karen Mylerberg (b) (4)	30 Jul 2020 20:41:05

US3112030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:11:47

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '13:29'	Karen Mylerberg (b) (4)	30 Jul 2020 20:41:05

US3112030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:11:47

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User entered '30 Jul 2020 13:29'	System	30 Jul 2020 20:41:05

US3112030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:11:47

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered 'Left Arm (LEFT ARM)'	Karen Mylerberg (b) (4)	30 Jul 2020 20:41:05

US3112030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:11:47

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User entered 'ONCE'	System	30 Jul 2020 20:41:05

US3112030

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:11:47

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User entered 'INTRAMUSCULAR'	System	30 Jul 2020 20:41:05

US3112030

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:11:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	01 Aug 2020 00:55:32

US3112030

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:11:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '30 Jul 2020'	Karen Mylerberg (b) (4)	01 Aug 2020 00:55:32

US3112030

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:11:47

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '13:00'	Karen Mylerberg (b) (4)	01 Aug 2020 00:55:32

US3112030

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:11:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User entered '30 Jul 2020 13:00'	System	01 Aug 2020 00:55:32

US3112030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:11:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '30 Jul 2020'	Karen Mylerberg (b) (4)	01 Aug 2020 00:55:47

US3112030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:11:47

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karen Mylerberg (b) (4)	01 Aug 2020 00:55:47

US3112030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:11:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	01 Aug 2020 00:55:47

US3112030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:11:47

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '12:45'	Karen Mylerberg (b) (4)	01 Aug 2020 00:55:47

US3112030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:11:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User entered '30 Jul 2020 12:45'	System	01 Aug 2020 00:55:47

US3112030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:11:47

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karen Mylerberg (b) (4)	01 Aug 2020 00:55:47

US3112030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:11:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered 'No (N)'	Karen Mylerberg (b) (4)	01 Aug 2020 00:55:47

US3112030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:11:47

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered empty.	Karen Mylerberg (b) (4)	01 Aug 2020 00:55:47

US3112030

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:11:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User entered empty.	System	01 Aug 2020 00:55:47

US3112030

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:11:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	01 Aug 2020 00:55:54

US3112030

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:11:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User entered 'I'	System	01 Aug 2020 00:55:54

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	30 Jul 2020 20:41:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-07-30T14:05:16', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '008bf405-57c6-4811-930e-28040b65954e' User entered 'Yes (Y)'	System	30 Jul 2020 21:06:00
	System	30 Jul 2020 21:06:00

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-07-30T14:05:39', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '008bf405-57c6-4811-930e-28040b65954e' User entered '98.0'	System	30 Jul 2020 21:06:00
	System	30 Jul 2020 21:06:00

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-07-30T14:05:45', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '008bf405-57c6-4811-930e-28040b65954e' User entered 'No (N)'	System	30 Jul 2020 21:06:00
	System	30 Jul 2020 21:06:00

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-07-30T14:05:56', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '008bf405-57c6-4811-930e-28040b65954e' User entered '30 Jul 2020 14:05'	System	30 Jul 2020 21:06:00
	System	30 Jul 2020 21:06:00

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '30 Jul 2020 13:49'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '30 Jul 2020 16:19'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	30 Jul 2020 20:41:05
User entered 'Day 1, after vaccination (at home)'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-07-30T20:55:20', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'cc595983-ae1a-46f4-a90d-264d379ccd5c' User entered 'Yes (Y)'	System	31 Jul 2020 03:56:28
	System	31 Jul 2020 03:56:28

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-07-30T20:55:31', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'cc595983-ae1a-46f4-a90d-264d379ccd5c' User entered '98.1'	System	31 Jul 2020 03:56:28
	System	31 Jul 2020 03:56:28

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-07-30T20:56:02', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'cc595983-ae1a-46f4-a90d-264d379ccd5c' User entered 'No (N)'	System	31 Jul 2020 03:56:28
	System	31 Jul 2020 03:56:28

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-07-30T20:56:25', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'cc595983-ae1a-46f4-a90d-264d379ccd5c' User entered '30 Jul 2020 20:56'	System	31 Jul 2020 03:56:28
	System	31 Jul 2020 03:56:28

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '30 Jul 2020 17:14'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '31 Jul 2020 11:59'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	30 Jul 2020 20:41:05
User entered 'Day 2'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:11:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-07-31T13:10:54', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'd7492e24-be41-48fc-9d2c-9732911ac9a1' User entered 'Yes (Y)'	System	31 Jul 2020 20:11:40
	System	31 Jul 2020 20:11:40

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:11:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-07-31T13:11:03', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'd7492e24-be41-48fc-9d2c-9732911ac9a1' User entered '97.4'	System	31 Jul 2020 20:11:40
	System	31 Jul 2020 20:11:40

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-07-31T13:11:26', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'd7492e24-be41-48fc-9d2c-9732911ac9a1' User entered 'No (N)'	System	31 Jul 2020 20:11:40
	System	31 Jul 2020 20:11:40

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:11:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-07-31T13:11:38', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'd7492e24-be41-48fc-9d2c-9732911ac9a1' User entered '31 Jul 2020 13:11'	System	31 Jul 2020 20:11:40
	System	31 Jul 2020 20:11:40

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:11:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '31 Jul 2020 12:00'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:11:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '01 Aug 2020 11:59'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	30 Jul 2020 20:41:05
User entered 'Day 3'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:11:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-01T12:11:27', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'a45e6503-61d7-4342-8786-5027ce00c8be' User entered 'Yes (Y)'	System	01 Aug 2020 19:12:22
	System	01 Aug 2020 19:12:22

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:11:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-01T12:11:57', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'a45e6503-61d7-4342-8786-5027ce00c8be' User entered '97.3'	System	01 Aug 2020 19:12:22
	System	01 Aug 2020 19:12:22

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-01T12:12:04', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'a45e6503-61d7-4342-8786-5027ce00c8be' User entered 'No (N)'	System	01 Aug 2020 19:12:22
	System	01 Aug 2020 19:12:22

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:11:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-01T12:12:17', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'a45e6503-61d7-4342-8786-5027ce00c8be' User entered '01 Aug 2020 12:12'	System	01 Aug 2020 19:12:22
	System	01 Aug 2020 19:12:22

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:11:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '01 Aug 2020 12:00'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:11:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '02 Aug 2020 11:59'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	30 Jul 2020 20:41:05
User entered 'Day 4'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:11:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-02T20:43:03', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'f3e40b43-acaf-4d76-950b-5ba3eed70b33' User entered 'No (N)'	System	03 Aug 2020 03:43:34
	System	03 Aug 2020 03:43:34

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-02T20:43:08', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'f3e40b43-acaf-4d76-950b-5ba3eed70b33'	System	03 Aug 2020 03:43:34
User entered 'No (N)'	System	03 Aug 2020 03:43:34

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:11:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-02T20:43:31', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'f3e40b43-acaf-4d76-950b-5ba3eed70b33' User entered '02 Aug 2020 20:43'	System	03 Aug 2020 03:43:34
	System	03 Aug 2020 03:43:34

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:11:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '02 Aug 2020 12:00'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:11:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '03 Aug 2020 11:59'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	30 Jul 2020 20:41:05
User entered 'Day 5'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:11:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-03T12:14:06', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '5638aef1-a106-446a-bc12-b9cb12f1f93a' User entered 'Yes (Y)'	System	03 Aug 2020 19:14:31
	System	03 Aug 2020 19:14:31

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:11:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-03T12:14:14', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '5638aef1-a106-446a-bc12-b9cb12f1f93a' User entered '97.5'	System	03 Aug 2020 19:14:31
	System	03 Aug 2020 19:14:31

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-03T12:14:19', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '5638aef1-a106-446a-bc12-b9cb12f1f93a' User entered 'No (N)'	System	03 Aug 2020 19:14:31
	System	03 Aug 2020 19:14:31

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:11:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-03T12:14:29', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '5638aef1-a106-446a-bc12-b9cb12f1f93a' User entered '03 Aug 2020 12:14'	System	03 Aug 2020 19:14:31
	System	03 Aug 2020 19:14:31

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:11:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '03 Aug 2020 12:00'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:11:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '04 Aug 2020 11:59'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	30 Jul 2020 20:41:05
User entered 'Day 6'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:11:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-04T14:26:30', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'ce111ad6-6472-4c76-bdde-b2ddf38547e8' User entered 'Yes (Y)'	System	04 Aug 2020 21:27:04
	System	04 Aug 2020 21:27:04

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:11:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-04T14:26:42', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'ce111ad6-6472-4c76-bdde-b2ddf38547e8' User entered '97.8'	System	04 Aug 2020 21:27:04
	System	04 Aug 2020 21:27:04

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-04T14:26:45', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'ce111ad6-6472-4c76-bdde-b2ddf38547e8' User entered 'No (N)'	System	04 Aug 2020 21:27:04
	System	04 Aug 2020 21:27:04

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:11:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-04T14:27:02', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'ce111ad6-6472-4c76-bdde-b2ddf38547e8' User entered '04 Aug 2020 14:27'	System	04 Aug 2020 21:27:04
	System	04 Aug 2020 21:27:04

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:11:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '04 Aug 2020 12:00'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:11:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '05 Aug 2020 11:59'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	30 Jul 2020 20:41:05
User entered 'Day 7'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:11:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-05T22:46:04', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '953dedff-981c-48c2-9174-61e60061274f' User entered 'Yes (Y)'	System	06 Aug 2020 05:46:18
	System	06 Aug 2020 05:46:18

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:11:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-05T22:46:10', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '953dedff-981c-48c2-9174-61e60061274f' User entered '98.1'	System	06 Aug 2020 05:46:18
	System	06 Aug 2020 05:46:18

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-05T22:46:14', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '953dedff-981c-48c2-9174-61e60061274f' User entered 'No (N)'	System	06 Aug 2020 05:46:18
	System	06 Aug 2020 05:46:18

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:11:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-05T22:46:17', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '953dedff-981c-48c2-9174-61e60061274f' User entered '05 Aug 2020 22:46'	System	06 Aug 2020 05:46:18
	System	06 Aug 2020 05:46:18

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:11:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '05 Aug 2020 12:00'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:11:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '06 Aug 2020 11:59'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	30 Jul 2020 20:41:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-07-30T14:07:10', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'b25cd583-6a28-41a3-acaa-2e85ddbec366'	System	30 Jul 2020 21:08:07
User entered 'None (1)'	System	30 Jul 2020 21:08:07

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-07-30T14:07:15', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'b25cd583-6a28-41a3-acaa-2e85ddbec366'	System	30 Jul 2020 21:08:07
User entered 'No (N)'	System	30 Jul 2020 21:08:07

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-07-30T14:07:30', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'b25cd583-6a28-41a3-acaa-2e85ddbec366' User entered 'No (N)'	System	30 Jul 2020 21:08:07
	System	30 Jul 2020 21:08:07

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-07-30T14:07:51', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'b25cd583-6a28-41a3-acaa-2e85ddbec366'	System	30 Jul 2020 21:08:07
User entered 'None (1)'	System	30 Jul 2020 21:08:07

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-07-30T14:08:03', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'b25cd583-6a28-41a3-acaa-2e85ddbec366'	System	30 Jul 2020 21:08:07
User entered '30 Jul 2020 14:08'	System	30 Jul 2020 21:08:07

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '30 Jul 2020 13:49'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '30 Jul 2020 16:19'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	30 Jul 2020 20:41:05
User entered 'Day 1, after vaccination (at home)'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-07-30T20:59:00', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '779a5a68-a447-4842-8037-446c60e6a3ae' User entered 'None (1)'	System	31 Jul 2020 03:59:13
	System	31 Jul 2020 03:59:13

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-07-30T20:57:56', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '779a5a68-a447-4842-8037-446c60e6a3ae' User entered 'No (N)'	System	31 Jul 2020 03:59:13
	System	31 Jul 2020 03:59:13

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-07-30T20:58:03', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '779a5a68-a447-4842-8037-446c60e6a3ae' User entered 'No (N)'	System	31 Jul 2020 03:59:13
	System	31 Jul 2020 03:59:13

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-07-30T20:58:38', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '779a5a68-a447-4842-8037-446c60e6a3ae'	System	31 Jul 2020 03:59:13
User entered 'None (1)'	System	31 Jul 2020 03:59:13

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-07-30T20:59:08', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '779a5a68-a447-4842-8037-446c60e6a3ae' User entered '30 Jul 2020 20:59'	System	31 Jul 2020 03:59:13
	System	31 Jul 2020 03:59:13

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '30 Jul 2020 17:14'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '31 Jul 2020 11:59'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	30 Jul 2020 20:41:05
User entered 'Day 2'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:11:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-07-31T13:11:47', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'f63b956f-7389-430a-8bba-ae297ec86454'	System	31 Jul 2020 20:12:24
User entered 'None (1)'	System	31 Jul 2020 20:12:24

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:11:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-07-31T13:11:51', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'f63b956f-7389-430a-8bba-ae297ec86454' User entered 'No (N)'	System	31 Jul 2020 20:12:24
	System	31 Jul 2020 20:12:24

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-07-31T13:11:59', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'f63b956f-7389-430a-8bba-ae297ec86454' User entered 'No (N)'	System	31 Jul 2020 20:12:24
	System	31 Jul 2020 20:12:24

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:11:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-07-31T13:12:04', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'f63b956f-7389-430a-8bba-ae297ec86454'	System	31 Jul 2020 20:12:24
User entered 'None (1)'	System	31 Jul 2020 20:12:24

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:11:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-07-31T13:12:23', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'f63b956f-7389-430a-8bba-ae297ec86454' User entered '31 Jul 2020 13:12'	System	31 Jul 2020 20:12:24
	System	31 Jul 2020 20:12:24

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:11:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '31 Jul 2020 12:00'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:11:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '01 Aug 2020 11:59'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	30 Jul 2020 20:41:05
User entered 'Day 3'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:11:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-01T12:12:26', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'd9ca0de3-fe8d-442b-b8f3-73caa694a0e2'	System	01 Aug 2020 19:13:17
User entered 'None (1)'	System	01 Aug 2020 19:13:17

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:11:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-01T12:12:40', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'd9ca0de3-fe8d-442b-b8f3-73caa694a0e2'	System	01 Aug 2020 19:13:17
User entered 'No (N)'	System	01 Aug 2020 19:13:17

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-01T12:12:51', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'd9ca0de3-fe8d-442b-b8f3-73caa694a0e2'	System	01 Aug 2020 19:13:17
User entered 'No (N)'	System	01 Aug 2020 19:13:17

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:11:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-01T12:13:03', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'd9ca0de3-fe8d-442b-b8f3-73caa694a0e2'	System	01 Aug 2020 19:13:17
User entered 'None (1)'	System	01 Aug 2020 19:13:17

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:11:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-01T12:13:14', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'd9ca0de3-fe8d-442b-b8f3-73caa694a0e2'	System	01 Aug 2020 19:13:17
User entered '01 Aug 2020 12:13'	System	01 Aug 2020 19:13:17

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:11:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '01 Aug 2020 12:00'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:11:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '02 Aug 2020 11:59'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	30 Jul 2020 20:41:05
User entered 'Day 4'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:11:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-02T20:43:40', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '56c4f9ad-0ae4-44cb-a3a2-1820aec86cb3'	System	03 Aug 2020 03:44:23
User entered 'None (1)'	System	03 Aug 2020 03:44:23

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:11:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-02T20:43:45', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '56c4f9ad-0ae4-44cb-a3a2-1820aec86cb3'	System	03 Aug 2020 03:44:23
User entered 'No (N)'	System	03 Aug 2020 03:44:23

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-02T20:43:49', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '56c4f9ad-0ae4-44cb-a3a2-1820aec86cb3'	System	03 Aug 2020 03:44:23
User entered 'No (N)'	System	03 Aug 2020 03:44:23

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:11:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-02T20:43:54', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '56c4f9ad-0ae4-44cb-a3a2-1820aec86cb3'	System	03 Aug 2020 03:44:23
User entered 'None (1)'	System	03 Aug 2020 03:44:23

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:11:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-02T20:44:21', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '56c4f9ad-0ae4-44cb-a3a2-1820aec86cb3' User entered '02 Aug 2020 20:44'	System	03 Aug 2020 03:44:23
	System	03 Aug 2020 03:44:23

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:11:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '02 Aug 2020 12:00'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:11:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '03 Aug 2020 11:59'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	30 Jul 2020 20:41:05
User entered 'Day 5'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:11:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-03T12:14:36', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '859f6489-ccec-4cf2-a0c0-fe1d982dd20b'	System	03 Aug 2020 19:14:59
User entered 'None (1)'	System	03 Aug 2020 19:14:59

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:11:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-03T12:14:41', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '859f6489-ccec-4cf2-a0c0-fe1d982dd20b' User entered 'No (N)'	System	03 Aug 2020 19:14:59
	System	03 Aug 2020 19:14:59

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-03T12:14:44', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '859f6489-ccec-4cf2-a0c0-fe1d982dd20b' User entered 'No (N)'	System	03 Aug 2020 19:14:59
	System	03 Aug 2020 19:14:59

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:11:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-03T12:14:49', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '859f6489-ccec-4cf2-a0c0-fe1d982dd20b'	System	03 Aug 2020 19:14:59
User entered 'None (1)'	System	03 Aug 2020 19:14:59

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:11:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-03T12:14:56', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '859f6489-ccec-4cf2-a0c0-fe1d982dd20b' User entered '03 Aug 2020 12:14'	System	03 Aug 2020 19:14:59
	System	03 Aug 2020 19:14:59

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:11:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '03 Aug 2020 12:00'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:11:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '04 Aug 2020 11:59'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	30 Jul 2020 20:41:05
User entered 'Day 6'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:11:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-04T14:27:09', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '3a793a94-fcb4-4a7b-b3fc-e0a95b7dbc51' User entered 'None (1)'	System	04 Aug 2020 21:27:34
	System	04 Aug 2020 21:27:34

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:11:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-04T14:27:15', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '3a793a94-fcb4-4a7b-b3fc-e0a95b7dbc51' User entered 'No (N)'	System	04 Aug 2020 21:27:34
	System	04 Aug 2020 21:27:34

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-04T14:27:18', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '3a793a94-fcb4-4a7b-b3fc-e0a95b7dbc51' User entered 'No (N)'	System	04 Aug 2020 21:27:34
	System	04 Aug 2020 21:27:34

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:11:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-04T14:27:26', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '3a793a94-fcb4-4a7b-b3fc-e0a95b7dbc51' User entered 'None (1)'	System	04 Aug 2020 21:27:34
	System	04 Aug 2020 21:27:34

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:11:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-04T14:27:32', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '3a793a94-fcb4-4a7b-b3fc-e0a95b7dbc51' User entered '04 Aug 2020 14:27'	System	04 Aug 2020 21:27:34
	System	04 Aug 2020 21:27:34

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:11:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '04 Aug 2020 12:00'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:11:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '05 Aug 2020 11:59'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	30 Jul 2020 20:41:05
User entered 'Day 7'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:11:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-05T22:46:32', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'be523516-8f4d-4f09-9957-e88bbb0674b6'	System	06 Aug 2020 05:46:57
User entered 'None (1)'	System	06 Aug 2020 05:46:57

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:11:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-05T22:46:36', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'be523516-8f4d-4f09-9957-e88bbb0674b6'	System	06 Aug 2020 05:46:57
User entered 'No (N)'	System	06 Aug 2020 05:46:57

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-05T22:46:39', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'be523516-8f4d-4f09-9957-e88bbb0674b6' User entered 'No (N)'	System	06 Aug 2020 05:46:57
	System	06 Aug 2020 05:46:57

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:11:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-05T22:46:43', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'be523516-8f4d-4f09-9957-e88bbb0674b6'	System	06 Aug 2020 05:46:57
User entered 'None (1)'	System	06 Aug 2020 05:46:57

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:11:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-05T22:46:53', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'be523516-8f4d-4f09-9957-e88bbb0674b6' User entered '05 Aug 2020 22:46'	System	06 Aug 2020 05:46:57
	System	06 Aug 2020 05:46:57

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:11:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '05 Aug 2020 12:00'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:11:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '06 Aug 2020 11:59'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	30 Jul 2020 20:41:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-07-30T14:08:17', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'af4496f0-0c07-4aa7-babf-d57f5197b9fe' User entered 'None (0)'	System	30 Jul 2020 21:09:10
	System	30 Jul 2020 21:09:10

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-07-30T14:08:23', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'af4496f0-0c07-4aa7-babf-d57f5197b9fe' User entered 'None (0)'	System	30 Jul 2020 21:09:10
	System	30 Jul 2020 21:09:10

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-07-30T14:08:27', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'af4496f0-0c07-4aa7-babf-d57f5197b9fe' User entered 'None (0)'	System	30 Jul 2020 21:09:10
	System	30 Jul 2020 21:09:10

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-07-30T14:08:35', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'af4496f0-0c07-4aa7-babf-d57f5197b9fe' User entered 'None (0)'	System	30 Jul 2020 21:09:10
	System	30 Jul 2020 21:09:10

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-07-30T14:08:41', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'af4496f0-0c07-4aa7-babf-d57f5197b9fe' User entered 'None (0)'	System	30 Jul 2020 21:09:10
	System	30 Jul 2020 21:09:10

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-07-30T14:08:46', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'af4496f0-0c07-4aa7-babf-d57f5197b9fe' User entered 'None (0)'	System	30 Jul 2020 21:09:10
	System	30 Jul 2020 21:09:10

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-07-30T14:08:59', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'af4496f0-0c07-4aa7-babf-d57f5197b9fe' User entered 'No (N)'	System	30 Jul 2020 21:09:10
	System	30 Jul 2020 21:09:10

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-07-30T14:09:07', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'af4496f0-0c07-4aa7-babf-d57f5197b9fe' User entered '30 Jul 2020 14:09'	System	30 Jul 2020 21:09:10
	System	30 Jul 2020 21:09:10

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '30 Jul 2020 13:49'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '30 Jul 2020 16:19'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	30 Jul 2020 20:41:05
User entered 'Day 1, after vaccination (at home)'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-07-30T21:00:12', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '0e514852-f8ac-49ac-ad9a-aa1385af9a6e' User entered 'None (0)'	System	31 Jul 2020 04:02:32
	System	31 Jul 2020 04:02:32

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-07-30T21:00:27', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '0e514852-f8ac-49ac-ad9a-aa1385af9a6e' User entered 'None (0)'	System	31 Jul 2020 04:02:32
	System	31 Jul 2020 04:02:32

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-07-30T21:00:31', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '0e514852-f8ac-49ac-ad9a-aa1385af9a6e' User entered 'None (0)'	System	31 Jul 2020 04:02:32
	System	31 Jul 2020 04:02:32

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-07-30T21:00:35', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '0e514852-f8ac-49ac-ad9a-aa1385af9a6e' User entered 'None (0)'	System	31 Jul 2020 04:02:32
	System	31 Jul 2020 04:02:32

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-07-30T21:00:41', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '0e514852-f8ac-49ac-ad9a-aa1385af9a6e' User entered 'None (0)'	System	31 Jul 2020 04:02:32
	System	31 Jul 2020 04:02:32

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-07-30T21:00:44', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '0e514852-f8ac-49ac-ad9a-aa1385af9a6e' User entered 'None (0)'	System	31 Jul 2020 04:02:32
	System	31 Jul 2020 04:02:32

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-07-30T21:01:26', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '0e514852-f8ac-49ac-ad9a-aa1385af9a6e' User entered 'No (N)'	System	31 Jul 2020 04:02:32
	System	31 Jul 2020 04:02:32

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-07-30T21:02:30', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '0e514852-f8ac-49ac-ad9a-aa1385af9a6e' User entered '30 Jul 2020 21:02'	System	31 Jul 2020 04:02:32
	System	31 Jul 2020 04:02:32

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '30 Jul 2020 17:14'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '31 Jul 2020 11:59'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	30 Jul 2020 20:41:05
User entered 'Day 2'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:11:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-07-31T13:12:32', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '2ad6158f-a6d7-4ccc-b8ca-a1a60fed8273' User entered 'None (0)'	System	31 Jul 2020 20:13:30
	System	31 Jul 2020 20:13:30

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:11:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-07-31T13:12:40', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '2ad6158f-a6d7-4ccc-b8ca-a1a60fed8273' User entered 'None (0)'	System	31 Jul 2020 20:13:30
	System	31 Jul 2020 20:13:30

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:11:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-07-31T13:12:47', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '2ad6158f-a6d7-4ccc-b8ca-a1a60fed8273' User entered 'None (0)'	System	31 Jul 2020 20:13:30
	System	31 Jul 2020 20:13:30

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:11:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-07-31T13:12:52', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '2ad6158f-a6d7-4ccc-b8ca-a1a60fed8273' User entered 'None (0)'	System	31 Jul 2020 20:13:30
	System	31 Jul 2020 20:13:30

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:11:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-07-31T13:12:55', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '2ad6158f-a6d7-4ccc-b8ca-a1a60fed8273' User entered 'None (0)'	System	31 Jul 2020 20:13:30
	System	31 Jul 2020 20:13:30

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:11:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-07-31T13:12:57', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '2ad6158f-a6d7-4ccc-b8ca-a1a60fed8273' User entered 'None (0)'	System	31 Jul 2020 20:13:30
	System	31 Jul 2020 20:13:30

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-07-31T13:13:03', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '2ad6158f-a6d7-4ccc-b8ca-a1a60fed8273' User entered 'No (N)'	System	31 Jul 2020 20:13:30
	System	31 Jul 2020 20:13:30

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:11:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-07-31T13:13:28', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '2ad6158f-a6d7-4ccc-b8ca-a1a60fed8273' User entered '31 Jul 2020 13:13'	System	31 Jul 2020 20:13:30
	System	31 Jul 2020 20:13:30

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:11:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '31 Jul 2020 12:00'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:11:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '01 Aug 2020 11:59'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	30 Jul 2020 20:41:05
User entered 'Day 3'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:11:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-01T12:13:20', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '0c20a4d3-68aa-4793-bbad-0b86e7483dda' User entered 'None (0)'	System	01 Aug 2020 19:14:15
	System	01 Aug 2020 19:14:15

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:11:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-01T12:13:27', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '0c20a4d3-68aa-4793-bbad-0b86e7483dda' User entered 'None (0)'	System	01 Aug 2020 19:14:15
	System	01 Aug 2020 19:14:15

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:11:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-01T12:13:34', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '0c20a4d3-68aa-4793-bbad-0b86e7483dda' User entered 'None (0)'	System	01 Aug 2020 19:14:15
	System	01 Aug 2020 19:14:15

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:11:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-01T12:13:40', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '0c20a4d3-68aa-4793-bbad-0b86e7483dda' User entered 'None (0)'	System	01 Aug 2020 19:14:15
	System	01 Aug 2020 19:14:15

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:11:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-01T12:13:45', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '0c20a4d3-68aa-4793-bbad-0b86e7483dda' User entered 'None (0)'	System	01 Aug 2020 19:14:15
	System	01 Aug 2020 19:14:15

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:11:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-01T12:13:56', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '0c20a4d3-68aa-4793-bbad-0b86e7483dda' User entered 'None (0)'	System	01 Aug 2020 19:14:15
	System	01 Aug 2020 19:14:15

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-01T12:14:01', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '0c20a4d3-68aa-4793-bbad-0b86e7483dda' User entered 'No (N)'	System	01 Aug 2020 19:14:15
	System	01 Aug 2020 19:14:15

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:11:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-01T12:14:13', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '0c20a4d3-68aa-4793-bbad-0b86e7483dda' User entered '01 Aug 2020 12:14'	System	01 Aug 2020 19:14:15
	System	01 Aug 2020 19:14:15

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:11:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '01 Aug 2020 12:00'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:11:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '02 Aug 2020 11:59'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	30 Jul 2020 20:41:05
User entered 'Day 4'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:11:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-02T20:44:27', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '951d9b83-406d-46a6-8c7c-fd904c4bda2f' User entered 'None (0)'	System	03 Aug 2020 03:45:15
	System	03 Aug 2020 03:45:15

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:11:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-02T20:44:31', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '951d9b83-406d-46a6-8c7c-fd904c4bda2f' User entered 'None (0)'	System	03 Aug 2020 03:45:15
	System	03 Aug 2020 03:45:15

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:11:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-02T20:44:38', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '951d9b83-406d-46a6-8c7c-fd904c4bda2f' User entered 'None (0)'	System	03 Aug 2020 03:45:15
	System	03 Aug 2020 03:45:15

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:11:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-02T20:44:42', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '951d9b83-406d-46a6-8c7c-fd904c4bda2f' User entered 'None (0)'	System	03 Aug 2020 03:45:15
	System	03 Aug 2020 03:45:15

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:11:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-02T20:44:45', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '951d9b83-406d-46a6-8c7c-fd904c4bda2f' User entered 'None (0)'	System	03 Aug 2020 03:45:15
	System	03 Aug 2020 03:45:15

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:11:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-02T20:44:48', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '951d9b83-406d-46a6-8c7c-fd904c4bda2f' User entered 'None (0)'	System	03 Aug 2020 03:45:15
	System	03 Aug 2020 03:45:15

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-02T20:44:54', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '951d9b83-406d-46a6-8c7c-fd904c4bda2f' User entered 'No (N)'	System	03 Aug 2020 03:45:15
	System	03 Aug 2020 03:45:15

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:11:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-02T20:45:10', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '951d9b83-406d-46a6-8c7c-fd904c4bda2f' User entered '02 Aug 2020 20:45'	System	03 Aug 2020 03:45:15
	System	03 Aug 2020 03:45:15

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:11:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '02 Aug 2020 12:00'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:11:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '03 Aug 2020 11:59'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	30 Jul 2020 20:41:05
User entered 'Day 5'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:11:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-03T12:15:01', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '789178e6-d091-4443-bd37-f2f84ab4490a' User entered 'None (0)'	System	03 Aug 2020 19:15:31
	System	03 Aug 2020 19:15:31

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:11:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-03T12:15:04', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '789178e6-d091-4443-bd37-f2f84ab4490a' User entered 'None (0)'	System	03 Aug 2020 19:15:31
	System	03 Aug 2020 19:15:31

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:11:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-03T12:15:07', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '789178e6-d091-4443-bd37-f2f84ab4490a' User entered 'None (0)'	System	03 Aug 2020 19:15:31
	System	03 Aug 2020 19:15:31

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:11:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-03T12:15:11', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '789178e6-d091-4443-bd37-f2f84ab4490a' User entered 'None (0)'	System	03 Aug 2020 19:15:31
	System	03 Aug 2020 19:15:31

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:11:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-03T12:15:14', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '789178e6-d091-4443-bd37-f2f84ab4490a' User entered 'None (0)'	System	03 Aug 2020 19:15:31
	System	03 Aug 2020 19:15:31

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:11:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-03T12:15:16', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '789178e6-d091-4443-bd37-f2f84ab4490a' User entered 'None (0)'	System	03 Aug 2020 19:15:31
	System	03 Aug 2020 19:15:31

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-03T12:15:22', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '789178e6-d091-4443-bd37-f2f84ab4490a' User entered 'No (N)'	System	03 Aug 2020 19:15:31
	System	03 Aug 2020 19:15:31

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:11:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-03T12:15:29', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '789178e6-d091-4443-bd37-f2f84ab4490a' User entered '03 Aug 2020 12:15'	System	03 Aug 2020 19:15:31
	System	03 Aug 2020 19:15:31

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:11:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '03 Aug 2020 12:00'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:11:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '04 Aug 2020 11:59'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	30 Jul 2020 20:41:05
User entered 'Day 6'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:11:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-04T14:27:39', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '8815eb4f-6e82-4579-9e02-d843a4b72e6c' User entered 'None (0)'	System	04 Aug 2020 21:28:19
	System	04 Aug 2020 21:28:19

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:11:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-04T14:27:42', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '8815eb4f-6e82-4579-9e02-d843a4b72e6c' User entered 'None (0)'	System	04 Aug 2020 21:28:19
	System	04 Aug 2020 21:28:19

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:11:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-04T14:27:45', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '8815eb4f-6e82-4579-9e02-d843a4b72e6c' User entered 'None (0)'	System	04 Aug 2020 21:28:19
	System	04 Aug 2020 21:28:19

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:11:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-04T14:27:48', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '8815eb4f-6e82-4579-9e02-d843a4b72e6c' User entered 'None (0)'	System	04 Aug 2020 21:28:19
	System	04 Aug 2020 21:28:19

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:11:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-04T14:27:52', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '8815eb4f-6e82-4579-9e02-d843a4b72e6c' User entered 'None (0)'	System	04 Aug 2020 21:28:19
	System	04 Aug 2020 21:28:19

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:11:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-04T14:27:54', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '8815eb4f-6e82-4579-9e02-d843a4b72e6c' User entered 'None (0)'	System	04 Aug 2020 21:28:19
	System	04 Aug 2020 21:28:19

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-04T14:27:58', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '8815eb4f-6e82-4579-9e02-d843a4b72e6c' User entered 'No (N)'	System	04 Aug 2020 21:28:19
	System	04 Aug 2020 21:28:19

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:11:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-04T14:28:01', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '8815eb4f-6e82-4579-9e02-d843a4b72e6c' User entered '04 Aug 2020 14:28'	System	04 Aug 2020 21:28:19
	System	04 Aug 2020 21:28:19

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:11:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '04 Aug 2020 12:00'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:11:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '05 Aug 2020 11:59'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	30 Jul 2020 20:41:05
User entered 'Day 7'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:11:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-05T22:48:00', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'dcd0fb75-dca0-4f05-b86d-a69c8bc16b0c' User entered 'None (0)'	System	06 Aug 2020 05:49:56
	System	06 Aug 2020 05:49:56

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:11:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-05T22:48:18', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'dcd0fb75-dca0-4f05-b86d-a69c8bc16b0c' User entered 'None (0)'	System	06 Aug 2020 05:49:56
	System	06 Aug 2020 05:49:56

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:11:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-05T22:47:22', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'dcd0fb75-dca0-4f05-b86d-a69c8bc16b0c' User entered 'None (0)'	System	06 Aug 2020 05:49:56
	System	06 Aug 2020 05:49:56

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:11:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-05T22:47:31', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'dcd0fb75-dca0-4f05-b86d-a69c8bc16b0c' User entered 'None (0)'	System	06 Aug 2020 05:49:56
	System	06 Aug 2020 05:49:56

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:11:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-05T22:48:48', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'dcd0fb75-dca0-4f05-b86d-a69c8bc16b0c'	System	06 Aug 2020 05:49:56
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	06 Aug 2020 05:49:56

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:11:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-05T22:47:37', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'dcd0fb75-dca0-4f05-b86d-a69c8bc16b0c' User entered 'None (0)'	System	06 Aug 2020 05:49:56
	System	06 Aug 2020 05:49:56

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-05T22:47:43', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'dcd0fb75-dca0-4f05-b86d-a69c8bc16b0c' User entered 'No (N)'	System	06 Aug 2020 05:49:56
	System	06 Aug 2020 05:49:56

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:11:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-05T22:49:52', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'dcd0fb75-dca0-4f05-b86d-a69c8bc16b0c' User entered '05 Aug 2020 22:49'	System	06 Aug 2020 05:49:56
	System	06 Aug 2020 05:49:56

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:11:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '05 Aug 2020 12:00'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:11:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '06 Aug 2020 11:59'	System	30 Jul 2020 20:41:05

US3112030

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	06 Aug 2020 05:49:56
User entered 'Day 8'	System	06 Aug 2020 05:49:56

US3112030

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 15:11:47

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13

US3112030

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 15:11:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13

US3112030

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 15:11:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '06 Aug 2020 12:00'	System	06 Aug 2020 05:49:56

US3112030

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 15:11:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 05:49:56

US3112030

Folder: Diary Dose 1 (1)

Form: Nausea_Day(9)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	06 Aug 2020 05:49:56
User entered 'Day 9'	System	06 Aug 2020 05:49:56

US3112030

Folder: Diary Dose 1 (1)

Form: Nausea_Day(9)

Generated On: 09 Jun 2021 15:11:47

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13

US3112030

Folder: Diary Dose 1 (1)

Form: Nausea_Day(9)

Generated On: 09 Jun 2021 15:11:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13

US3112030

Folder: Diary Dose 1 (1)

Form: Nausea_Day(9)

Generated On: 09 Jun 2021 15:11:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 05:49:56

US3112030

Folder: Diary Dose 1 (1)

Form: Nausea_Day(9)

Generated On: 09 Jun 2021 15:11:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 05:49:56

US3112030

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	06 Aug 2020 05:49:56
User entered 'Day 8'	System	06 Aug 2020 05:49:56

US3112030

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13

US3112030

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:11:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13

US3112030

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:11:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '06 Aug 2020 12:00'	System	06 Aug 2020 05:49:56

US3112030

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:11:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 05:49:56

US3112030

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	06 Aug 2020 05:49:56
User entered 'Day 9'	System	06 Aug 2020 05:49:56

US3112030

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13

US3112030

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:11:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13

US3112030

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:11:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 05:49:56

US3112030

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:11:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 05:49:56

US3112030

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:30:48
User entered 'Yes (Y)'	Laurie Han-Conrad (b) (4)	06 Aug 2020 18:20:46

US3112030

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:30:48
User entered '06 Aug 2020'	Laurie Han-Conrad (b) (4)	06 Aug 2020 18:20:46

US3112030

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:30:48
User entered 'Contact Made (CONTACT MADE)'	Laurie Han-Conrad (b) (4)	06 Aug 2020 18:20:46

US3112030

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:30:48
User entered empty.	Laurie Han-Conrad (b) (4)	06 Aug 2020 18:20:46

US3112030

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:30:48
User entered 'Yes (Y)'	Laurie Han-Conrad (b) (4)	06 Aug 2020 18:20:52

US3112030

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User entered 'I'	System	06 Aug 2020 18:20:52

US3112030

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:30:48
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	13 Aug 2020 21:39:12

US3112030

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:30:48
User entered '13 Aug 2020'	Karen Mylerberg (b) (4)	13 Aug 2020 21:39:12

US3112030

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:30:48
User entered 'Contact Made (CONTACT MADE)'	Karen Mylerberg (b) (4)	13 Aug 2020 21:39:12

US3112030

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:30:48
User entered empty.	Karen Mylerberg (b) (4)	13 Aug 2020 21:39:12

US3112030

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:30:48
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	13 Aug 2020 21:39:19

US3112030

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User entered 'I'	System	13 Aug 2020 21:39:19

US3112030

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:30:48
User entered 'Yes (Y)'	(b) (4) Nicolle Mendez (b) (4)	21 Aug 2020 17:53:44

US3112030

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:30:48
User entered '21 Aug 2020'	Nicolle Mendez (b) (4)	21 Aug 2020 17:53:44

US3112030

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:30:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Nicolle Mendez (b) (4)	21 Aug 2020 17:53:44

US3112030

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:30:48
User entered empty.	(b) (4) Nicolle Mendez (b) (4)	21 Aug 2020 17:53:44

US3112030

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:30:48
User entered 'Yes (Y)'	(b) (4) Nicolle Mendez (b) (4)	21 Aug 2020 17:53:50

US3112030

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User entered 'I'	System	21 Aug 2020 17:53:50

US3112030

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:11:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 19:29:29

US3112030

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '27 Aug 2020'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 19:29:29

US3112030

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 19:29:29

US3112030

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:11:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User entered 'VISIT2'	System	27 Aug 2020 19:29:29

US3112030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User accepted default value 'Pre-Dose (PREDOSE)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:05:24

US3112030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth	01 Sep 2020 18:05:24
	(b) (4)	

US3112030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '27 Aug 2020'	(b) (4) Matthew Musikanth	01 Sep 2020 18:05:24
	(b) (4)	

US3112030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '11:20'	(b) (4) Matthew Musikanth	01 Sep 2020 18:05:24
	(b) (4)	

US3112030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User entered '27 Aug 2020 11:20'	System	01 Sep 2020 18:05:24

US3112030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '98.6' F	(b) (4) Matthew Musikanth	01 Sep 2020 18:05:24
	(b) (4)	

US3112030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered 'Oral (Oral)'	(b) (4) Matthew Musikanth (b) (4)	01 Sep 2020 18:05:24

US3112030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered empty.	(b) (4) Matthew Musikanth	01 Sep 2020 18:05:24
	(b) (4)	

US3112030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '69'	Matthew Musikanth (b) (4)	01 Sep 2020 18:05:24

US3112030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User entered 'bpm'	System	01 Sep 2020 18:05:24

US3112030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '16'	(b) (4) Matthew Musikanth	01 Sep 2020 18:05:24
	(b) (4)	

US3112030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User entered 'breaths/min'	System	01 Sep 2020 18:05:24

US3112030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '113'	(b) (4) Matthew Musikanth	01 Sep 2020 18:05:24
	(b) (4)	

US3112030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User entered 'mmHg'	System	01 Sep 2020 18:05:24

US3112030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '64'	(b) (4) Matthew Musikanth	01 Sep 2020 18:05:24
	(b) (4)	

US3112030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User entered 'mmHg'	System	01 Sep 2020 18:05:24

US3112030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User accepted default value 'Post-Dose (POSTDOSE)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:05:24

US3112030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth	01 Sep 2020 18:05:24
	(b) (4)	

US3112030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '27 Aug 2020'	(b) (4) Matthew Musikanth	01 Sep 2020 18:05:24
	(b) (4)	

US3112030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '12:45'	Matthew Musikanth (b) (4)	01 Sep 2020 18:05:24

US3112030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User entered '27 Aug 2020 12:45'	System	01 Sep 2020 18:05:24

US3112030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '98.4' F	Matthew Musikanth (b) (4)	01 Sep 2020 18:05:24

US3112030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered 'Oral (Oral)'	(b) (4) Matthew Musikanth (b) (4)	01 Sep 2020 18:05:24

US3112030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered empty.	(b) (4) Matthew Musikanth	01 Sep 2020 18:05:24
	(b) (4)	

US3112030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '66'	(b) (4) Matthew Musikanth	01 Sep 2020 18:05:24
	(b) (4)	

US3112030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User entered 'bpm'	System	01 Sep 2020 18:05:24

US3112030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '16'	(b) (4) Matthew Musikanth	01 Sep 2020 18:05:24
	(b) (4)	

US3112030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User entered 'breaths/min'	System	01 Sep 2020 18:05:24

US3112030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '122'	(b) (4) Matthew Musikanth	01 Sep 2020 18:05:24
	(b) (4)	

US3112030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User entered 'mmHg'	System	01 Sep 2020 18:05:24

US3112030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '72'	(b) (4) Matthew Musikanth	01 Sep 2020 18:05:24
	(b) (4)	

US3112030

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User entered 'mmHg'	System	01 Sep 2020 18:05:24

US3112030

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:11:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Karen Mylerberg (b) (4)	01 Oct 2020 15:21:52
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Karen Mylerberg (b) (4)	01 Sep 2020 19:04:49
User entered 'Yes (Y)'	(b) (4)	
	Matthew Musikanth	01 Sep 2020 18:05:32
	(b) (4)	

US3112030

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:11:47

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '27 Aug 2020' reason for change: Data Entry Error	Karen Mylerberg (b) (4)	01 Oct 2020 15:21:52
User entered empty; reason for change Data Entry Error	Karen Mylerberg (b) (4)	01 Sep 2020 19:04:49
User entered '27 Aug 2020'	Matthew Musikanth (b) (4)	01 Sep 2020 18:05:32

US3112030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:11:47

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 19:29:46

US3112030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:11:47

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 19:29:46

US3112030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:11:47

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)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Aug 2020 19:29:46

US3112030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:11:47

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User entered 'MRNA-1273 OR PLACEBO'	System	27 Aug 2020 19:29:46

US3112030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:11:47

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '27 Aug 2020'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 19:29:46

US3112030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:11:47

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '12:12'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 19:29:46

US3112030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:11:47

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User entered '27 Aug 2020 12:12'	System	27 Aug 2020 19:29:46

US3112030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:11:47

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 19:29:46

US3112030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:11:47

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User entered 'ONCE'	System	27 Aug 2020 19:29:46

US3112030

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:11:47

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User entered 'INTRAMUSCULAR'	System	27 Aug 2020 19:29:46

US3112030

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:11:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered 'Yes (Y)'	(b) (4) Matthew Musikanth (b) (4)	01 Sep 2020 18:05:53

US3112030

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:11:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '27 Aug 2020'	(b) (4) Matthew Musikanth	01 Sep 2020 18:05:53
	(b) (4)	

US3112030

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:11:47

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '11:05'	(b) (4) Matthew Musikanth	01 Sep 2020 18:05:53
	(b) (4)	

US3112030

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:11:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User entered '27 Aug 2020 11:05'	System	01 Sep 2020 18:05:53

US3112030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:11:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '27 Aug 2020'	Matthew Musikanth (b) (4)	01 Sep 2020 18:06:09

US3112030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:11:47

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:06:09

US3112030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:11:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:06:09

US3112030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:11:47

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '11:36'	(b) (4) Matthew Musikanth	01 Sep 2020 18:06:09
	(b) (4)	

US3112030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:11:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User entered '27 Aug 2020 11:36'	System	01 Sep 2020 18:06:09

US3112030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:11:47

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:06:09

US3112030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:11:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered 'No (N)'	(b) (4) Matthew Musikanth (b) (4)	01 Sep 2020 18:06:09

US3112030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:11:47

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered empty.	Matthew Musikanth (b) (4)	01 Sep 2020 18:06:09

US3112030

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:11:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User entered empty.	System	01 Sep 2020 18:06:09

US3112030

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 19:29:51

US3112030

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User entered '1'	System	27 Aug 2020 19:29:51

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	27 Aug 2020 19:29:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-27T12:50:46', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '7e5d1a57-75c2-41ea-a580-6d4724e219a3' User entered 'Yes (Y)'	System	27 Aug 2020 19:51:50
	System	27 Aug 2020 19:51:50

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-27T12:50:55', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '7e5d1a57-75c2-41ea-a580-6d4724e219a3' User entered '98.4'	System	27 Aug 2020 19:51:50
	System	27 Aug 2020 19:51:50

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-27T12:51:00', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '7e5d1a57-75c2-41ea-a580-6d4724e219a3'	System	27 Aug 2020 19:51:50
User entered 'No (N)'	System	27 Aug 2020 19:51:50

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-27T12:51:21', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '7e5d1a57-75c2-41ea-a580-6d4724e219a3'	System	27 Aug 2020 19:51:50
User entered '27 Aug 2020 12:51'	System	27 Aug 2020 19:51:50

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '27 Aug 2020 12:32'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '27 Aug 2020 15:02'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	27 Aug 2020 19:29:46
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-27T23:10:01', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '88cf7868-a4c5-4c14-a76e-607853c1858f' User entered 'Yes (Y)'	System	28 Aug 2020 06:10:34
	System	28 Aug 2020 06:10:34

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-27T23:10:14', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '88cf7868-a4c5-4c14-a76e-607853c1858f' User entered '98.4'	System	28 Aug 2020 06:10:34
	System	28 Aug 2020 06:10:34

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-27T23:10:24', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '88cf7868-a4c5-4c14-a76e-607853c1858f' User entered 'No (N)'	System	28 Aug 2020 06:10:34
	System	28 Aug 2020 06:10:34

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-27T23:10:30', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '88cf7868-a4c5-4c14-a76e-607853c1858f' User entered '27 Aug 2020 23:10'	System	28 Aug 2020 06:10:34
	System	28 Aug 2020 06:10:34

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '27 Aug 2020 15:57'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	27 Aug 2020 19:29:46
User entered 'Day 2'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:11:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-28T13:09:57', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '3640d19d-e876-40a6-b60f-b912b58c1357' User entered 'Yes (Y)'	System	28 Aug 2020 20:10:29
	System	28 Aug 2020 20:10:29

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:11:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-28T13:10:06', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '3640d19d-e876-40a6-b60f-b912b58c1357' User entered '98.4'	System	28 Aug 2020 20:10:29
	System	28 Aug 2020 20:10:29

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-28T13:10:10', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '3640d19d-e876-40a6-b60f-b912b58c1357' User entered 'No (N)'	System	28 Aug 2020 20:10:29
	System	28 Aug 2020 20:10:29

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:11:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-28T13:10:25', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '3640d19d-e876-40a6-b60f-b912b58c1357' User entered '28 Aug 2020 13:10'	System	28 Aug 2020 20:10:29
	System	28 Aug 2020 20:10:29

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:11:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:11:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	27 Aug 2020 19:29:46
User entered 'Day 3'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:11:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-29T12:00:54', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'aef07643-c5b8-4f66-a18d-ba915510a5ca' User entered 'Yes (Y)'	System	29 Aug 2020 19:01:49
	System	29 Aug 2020 19:01:49

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:11:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-29T12:01:05', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'aef07643-c5b8-4f66-a18d-ba915510a5ca' User entered '97.8'	System	29 Aug 2020 19:01:49
	System	29 Aug 2020 19:01:49

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-29T12:01:33', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'aef07643-c5b8-4f66-a18d-ba915510a5ca'	System	29 Aug 2020 19:01:49
User entered 'No (N)'	System	29 Aug 2020 19:01:49

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:11:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-29T12:01:48', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'aef07643-c5b8-4f66-a18d-ba915510a5ca' User entered '29 Aug 2020 12:01'	System	29 Aug 2020 19:01:49
	System	29 Aug 2020 19:01:49

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:11:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:11:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	27 Aug 2020 19:29:46
User entered 'Day 4'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:11:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-30T12:06:34', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'f1ae6099-0b2f-48a5-bfaa-b22e9d6d4422'	System	30 Aug 2020 19:07:06
User entered 'Yes (Y)'	System	30 Aug 2020 19:07:06

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:11:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-30T12:06:41', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'f1ae6099-0b2f-48a5-bfaa-b22e9d6d4422'	System	30 Aug 2020 19:07:06
User entered '96.8'	System	30 Aug 2020 19:07:06

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-30T12:06:55', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'f1ae6099-0b2f-48a5-bfaa-b22e9d6d4422'	System	30 Aug 2020 19:07:06
User entered 'No (N)'	System	30 Aug 2020 19:07:06

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:11:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-30T12:07:03', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'f1ae6099-0b2f-48a5-bfaa-b22e9d6d4422'	System	30 Aug 2020 19:07:06
User entered '30 Aug 2020 12:07'	System	30 Aug 2020 19:07:06

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:11:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:11:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	27 Aug 2020 19:29:46
User entered 'Day 5'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:11:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-31T12:13:54', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'e313f959-51dc-4c7f-b672-004af62d3c26' User entered 'Yes (Y)'	System	31 Aug 2020 19:21:31
	System	31 Aug 2020 19:21:31

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:11:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-31T12:14:06', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'e313f959-51dc-4c7f-b672-004af62d3c26' User entered '97.7'	System	31 Aug 2020 19:21:31
	System	31 Aug 2020 19:21:31

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-31T12:14:11', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'e313f959-51dc-4c7f-b672-004af62d3c26'	System	31 Aug 2020 19:21:31
User entered 'No (N)'	System	31 Aug 2020 19:21:31

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:11:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-31T12:14:16', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'e313f959-51dc-4c7f-b672-004af62d3c26'	System	31 Aug 2020 19:21:31
User entered '31 Aug 2020 12:14'	System	31 Aug 2020 19:21:31

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:11:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:11:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	27 Aug 2020 19:29:46
User entered 'Day 6'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:11:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-09-01T12:44:34', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '037b587e-8f75-4c25-ae18-b999a9ef126b' User entered 'Yes (Y)'	System	01 Sep 2020 19:44:52
	System	01 Sep 2020 19:44:52

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:11:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-09-01T12:44:42', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '037b587e-8f75-4c25-ae18-b999a9ef126b' User entered '97.0'	System	01 Sep 2020 19:44:52
	System	01 Sep 2020 19:44:52

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-09-01T12:44:46', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '037b587e-8f75-4c25-ae18-b999a9ef126b' User entered 'No (N)'	System	01 Sep 2020 19:44:52
	System	01 Sep 2020 19:44:52

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:11:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-09-01T12:44:50', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '037b587e-8f75-4c25-ae18-b999a9ef126b' User entered '01 Sep 2020 12:44'	System	01 Sep 2020 19:44:52
	System	01 Sep 2020 19:44:52

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:11:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:11:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	27 Aug 2020 19:29:46
User entered 'Day 7'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:11:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-09-02T13:44:58', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '69334224-0f75-4d8c-b578-e0c5b6fcc09e' User entered 'No (N)'	System	02 Sep 2020 20:45:14
	System	02 Sep 2020 20:45:14

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-09-02T13:45:03', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '69334224-0f75-4d8c-b578-e0c5b6fcc09e' User entered 'No (N)'	System	02 Sep 2020 20:45:14
	System	02 Sep 2020 20:45:14

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:11:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-09-02T13:45:10', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '69334224-0f75-4d8c-b578-e0c5b6fcc09e' User entered '02 Sep 2020 13:45'	System	02 Sep 2020 20:45:14
	System	02 Sep 2020 20:45:14

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:11:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:11:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	27 Aug 2020 19:29:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-27T12:46:18', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'a1d7ca1d-47f9-4dc3-9ab8-4758024b962b' User entered 'None (1)'	System	27 Aug 2020 19:53:18
	System	27 Aug 2020 19:53:18

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-27T12:52:54', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'a1d7ca1d-47f9-4dc3-9ab8-4758024b962b' User entered 'No (N)'	System	27 Aug 2020 19:53:18
	System	27 Aug 2020 19:53:18

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-27T12:52:57', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'a1d7ca1d-47f9-4dc3-9ab8-4758024b962b' User entered 'No (N)'	System	27 Aug 2020 19:53:18
	System	27 Aug 2020 19:53:18

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-27T12:53:03', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'a1d7ca1d-47f9-4dc3-9ab8-4758024b962b' User entered 'None (1)'	System	27 Aug 2020 19:53:18
	System	27 Aug 2020 19:53:18

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-27T12:53:15', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'a1d7ca1d-47f9-4dc3-9ab8-4758024b962b' User entered '27 Aug 2020 12:53'	System	27 Aug 2020 19:53:18
	System	27 Aug 2020 19:53:18

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '27 Aug 2020 12:32'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '27 Aug 2020 15:02'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	27 Aug 2020 19:29:46
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-27T23:10:47', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '5ea7c9e7-5edc-49cf-a324-641459b7739b' User entered 'None (1)'	System	28 Aug 2020 06:11:23
	System	28 Aug 2020 06:11:23

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-27T23:10:52', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '5ea7c9e7-5edc-49cf-a324-641459b7739b' User entered 'No (N)'	System	28 Aug 2020 06:11:23
	System	28 Aug 2020 06:11:23

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-27T23:11:02', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '5ea7c9e7-5edc-49cf-a324-641459b7739b' User entered 'No (N)'	System	28 Aug 2020 06:11:23
	System	28 Aug 2020 06:11:23

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-27T23:11:08', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '5ea7c9e7-5edc-49cf-a324-641459b7739b' User entered 'None (1)'	System	28 Aug 2020 06:11:23
	System	28 Aug 2020 06:11:23

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-27T23:11:20', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '5ea7c9e7-5edc-49cf-a324-641459b7739b' User entered '27 Aug 2020 23:11'	System	28 Aug 2020 06:11:23
	System	28 Aug 2020 06:11:23

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '27 Aug 2020 15:57'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	27 Aug 2020 19:29:46
User entered 'Day 2'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:11:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-28T13:10:32', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '776c8be8-97b6-4d2a-acb8-fe1e58563b59'	System	28 Aug 2020 20:10:57
User entered 'None (1)'	System	28 Aug 2020 20:10:57

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:11:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-28T13:10:38', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '776c8be8-97b6-4d2a-acb8-fe1e58563b59' User entered 'No (N)'	System	28 Aug 2020 20:10:57
	System	28 Aug 2020 20:10:57

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-28T13:10:45', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '776c8be8-97b6-4d2a-acb8-fe1e58563b59' User entered 'No (N)'	System	28 Aug 2020 20:10:57
	System	28 Aug 2020 20:10:57

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:11:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-28T13:10:50', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '776c8be8-97b6-4d2a-acb8-fe1e58563b59'	System	28 Aug 2020 20:10:57
User entered 'None (1)'	System	28 Aug 2020 20:10:57

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:11:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-28T13:10:55', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '776c8be8-97b6-4d2a-acb8-fe1e58563b59' User entered '28 Aug 2020 13:10'	System	28 Aug 2020 20:10:57
	System	28 Aug 2020 20:10:57

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:11:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:11:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	27 Aug 2020 19:29:46
User entered 'Day 3'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:11:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-29T12:01:56', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '6d74a2cb-e5ba-4c45-8487-662e686e1850' User entered 'None (1)'	System	29 Aug 2020 19:02:29
	System	29 Aug 2020 19:02:29

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:11:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-29T12:02:00', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '6d74a2cb-e5ba-4c45-8487-662e686e1850' User entered 'No (N)'	System	29 Aug 2020 19:02:29
	System	29 Aug 2020 19:02:29

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-29T12:02:04', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '6d74a2cb-e5ba-4c45-8487-662e686e1850' User entered 'No (N)'	System	29 Aug 2020 19:02:29
	System	29 Aug 2020 19:02:29

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:11:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-29T12:02:14', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '6d74a2cb-e5ba-4c45-8487-662e686e1850' User entered 'None (1)'	System	29 Aug 2020 19:02:29
	System	29 Aug 2020 19:02:29

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:11:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-29T12:02:27', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '6d74a2cb-e5ba-4c45-8487-662e686e1850' User entered '29 Aug 2020 12:02'	System	29 Aug 2020 19:02:29
	System	29 Aug 2020 19:02:29

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:11:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:11:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	27 Aug 2020 19:29:46
User entered 'Day 4'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:11:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-30T12:07:23', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'c94e9431-7d8a-478d-a7a3-aa8e2f1650f3'	System	30 Aug 2020 19:07:42
User entered 'None (1)'	System	30 Aug 2020 19:07:42

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:11:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-30T12:07:21', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'c94e9431-7d8a-478d-a7a3-aa8e2f1650f3'	System	30 Aug 2020 19:07:42
User entered 'No (N)'	System	30 Aug 2020 19:07:42

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-30T12:07:27', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'c94e9431-7d8a-478d-a7a3-aa8e2f1650f3'	System	30 Aug 2020 19:07:42
User entered 'No (N)'	System	30 Aug 2020 19:07:42

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:11:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-30T12:07:34', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'c94e9431-7d8a-478d-a7a3-aa8e2f1650f3'	System	30 Aug 2020 19:07:42
User entered 'None (1)'	System	30 Aug 2020 19:07:42

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:11:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-30T12:07:40', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'c94e9431-7d8a-478d-a7a3-aa8e2f1650f3' User entered '30 Aug 2020 12:07'	System	30 Aug 2020 19:07:42
	System	30 Aug 2020 19:07:42

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:11:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:11:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	27 Aug 2020 19:29:46
User entered 'Day 5'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:11:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-31T12:14:22', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'eca64e40-db6a-45ef-9780-e5b43f46789a'	System	31 Aug 2020 19:21:48
User entered 'None (1)'	System	31 Aug 2020 19:21:48

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-31T12:14:26', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'eca64e40-db6a-45ef-9780-e5b43f46789a' User entered 'No (N)'	System	31 Aug 2020 19:21:48
	System	31 Aug 2020 19:21:48

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-31T12:14:29', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'eca64e40-db6a-45ef-9780-e5b43f46789a' User entered 'No (N)'	System	31 Aug 2020 19:21:48
	System	31 Aug 2020 19:21:48

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:11:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-31T12:14:34', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'eca64e40-db6a-45ef-9780-e5b43f46789a'	System	31 Aug 2020 19:21:48
User entered 'None (1)'	System	31 Aug 2020 19:21:48

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:11:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-31T12:14:37', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'eca64e40-db6a-45ef-9780-e5b43f46789a' User entered '31 Aug 2020 12:14'	System	31 Aug 2020 19:21:48
	System	31 Aug 2020 19:21:48

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:11:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:11:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	27 Aug 2020 19:29:46
User entered 'Day 6'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:11:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-09-01T12:44:55', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '243c945e-9cfe-4320-964e-d52c38fc208d' User entered 'None (1)'	System	01 Sep 2020 19:45:17
	System	01 Sep 2020 19:45:17

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:11:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-09-01T12:45:02', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '243c945e-9cfe-4320-964e-d52c38fc208d' User entered 'No (N)'	System	01 Sep 2020 19:45:17
	System	01 Sep 2020 19:45:17

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-09-01T12:45:05', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '243c945e-9cfe-4320-964e-d52c38fc208d' User entered 'No (N)'	System	01 Sep 2020 19:45:17
	System	01 Sep 2020 19:45:17

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:11:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-09-01T12:45:09', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '243c945e-9cfe-4320-964e-d52c38fc208d' User entered 'None (1)'	System	01 Sep 2020 19:45:17
	System	01 Sep 2020 19:45:17

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:11:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-09-01T12:45:14', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '243c945e-9cfe-4320-964e-d52c38fc208d' User entered '01 Sep 2020 12:45'	System	01 Sep 2020 19:45:17
	System	01 Sep 2020 19:45:17

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:11:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:11:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	27 Aug 2020 19:29:46
User entered 'Day 7'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:11:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-09-02T13:45:19', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '42d1d686-e1ad-4fb9-9a8f-13dc159d0960' User entered 'None (1)'	System	02 Sep 2020 20:45:37
	System	02 Sep 2020 20:45:37

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:11:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-09-02T13:45:22', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '42d1d686-e1ad-4fb9-9a8f-13dc159d0960' User entered 'No (N)'	System	02 Sep 2020 20:45:37
	System	02 Sep 2020 20:45:37

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-09-02T13:45:25', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '42d1d686-e1ad-4fb9-9a8f-13dc159d0960' User entered 'No (N)'	System	02 Sep 2020 20:45:37
	System	02 Sep 2020 20:45:37

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:11:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-09-02T13:45:29', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '42d1d686-e1ad-4fb9-9a8f-13dc159d0960' User entered 'None (1)'	System	02 Sep 2020 20:45:37
	System	02 Sep 2020 20:45:37

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:11:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-09-02T13:45:34', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '42d1d686-e1ad-4fb9-9a8f-13dc159d0960' User entered '02 Sep 2020 13:45'	System	02 Sep 2020 20:45:37
	System	02 Sep 2020 20:45:37

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:11:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:11:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	27 Aug 2020 19:29:46
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-27T12:53:27', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '0e0d019b-e5ad-4d45-bf37-83d36fed00ae' User entered 'None (0)'	System	27 Aug 2020 19:54:23
	System	27 Aug 2020 19:54:23

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-27T12:53:30', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '0e0d019b-e5ad-4d45-bf37-83d36fed00ae' User entered 'None (0)'	System	27 Aug 2020 19:54:23
	System	27 Aug 2020 19:54:23

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-27T12:53:34', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '0e0d019b-e5ad-4d45-bf37-83d36fed00ae' User entered 'None (0)'	System	27 Aug 2020 19:54:23
	System	27 Aug 2020 19:54:23

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-27T12:53:38', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '0e0d019b-e5ad-4d45-bf37-83d36fed00ae' User entered 'None (0)'	System	27 Aug 2020 19:54:23
	System	27 Aug 2020 19:54:23

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-27T12:53:51', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '0e0d019b-e5ad-4d45-bf37-83d36fed00ae' User entered 'None (0)'	System	27 Aug 2020 19:54:23
	System	27 Aug 2020 19:54:23

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-27T12:53:55', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '0e0d019b-e5ad-4d45-bf37-83d36fed00ae' User entered 'None (0)'	System	27 Aug 2020 19:54:23
	System	27 Aug 2020 19:54:23

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-27T12:54:04', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '0e0d019b-e5ad-4d45-bf37-83d36fed00ae' User entered 'No (N)'	System	27 Aug 2020 19:54:23
	System	27 Aug 2020 19:54:23

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-27T12:54:19', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '0e0d019b-e5ad-4d45-bf37-83d36fed00ae' User entered '27 Aug 2020 12:54'	System	27 Aug 2020 19:54:23
	System	27 Aug 2020 19:54:23

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '27 Aug 2020 12:32'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:11:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '27 Aug 2020 15:02'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	27 Aug 2020 19:29:46
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-27T16:18:36', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '67bc8d74-4a43-47be-a578-e0519a2db113' User entered 'None (0)'	System	28 Aug 2020 06:12:17
	System	28 Aug 2020 06:12:17

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-27T23:11:39', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '67bc8d74-4a43-47be-a578-e0519a2db113' User entered 'None (0)'	System	28 Aug 2020 06:12:17
	System	28 Aug 2020 06:12:17

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-27T23:11:44', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '67bc8d74-4a43-47be-a578-e0519a2db113' User entered 'None (0)'	System	28 Aug 2020 06:12:17
	System	28 Aug 2020 06:12:17

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-27T23:11:50', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '67bc8d74-4a43-47be-a578-e0519a2db113' User entered 'None (0)'	System	28 Aug 2020 06:12:17
	System	28 Aug 2020 06:12:17

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-27T23:11:56', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '67bc8d74-4a43-47be-a578-e0519a2db113' User entered 'None (0)'	System	28 Aug 2020 06:12:17
	System	28 Aug 2020 06:12:17

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-27T23:11:59', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '67bc8d74-4a43-47be-a578-e0519a2db113' User entered 'None (0)'	System	28 Aug 2020 06:12:17
	System	28 Aug 2020 06:12:17

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-27T23:12:09', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '67bc8d74-4a43-47be-a578-e0519a2db113' User entered 'No (N)'	System	28 Aug 2020 06:12:17
	System	28 Aug 2020 06:12:17

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-27T23:12:14', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '67bc8d74-4a43-47be-a578-e0519a2db113' User entered '27 Aug 2020 23:12'	System	28 Aug 2020 06:12:17
	System	28 Aug 2020 06:12:17

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '27 Aug 2020 15:57'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:11:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	27 Aug 2020 19:29:46
User entered 'Day 2'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:11:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-28T13:11:01', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '14f6bc8c-f51a-4cd0-992d-47b371f6a931' User entered 'None (0)'	System	28 Aug 2020 20:11:41
	System	28 Aug 2020 20:11:41

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:11:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-28T13:11:05', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '14f6bc8c-f51a-4cd0-992d-47b371f6a931' User entered 'None (0)'	System	28 Aug 2020 20:11:41
	System	28 Aug 2020 20:11:41

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:11:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-28T13:11:09', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '14f6bc8c-f51a-4cd0-992d-47b371f6a931' User entered 'None (0)'	System	28 Aug 2020 20:11:41
	System	28 Aug 2020 20:11:41

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:11:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-28T13:11:14', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '14f6bc8c-f51a-4cd0-992d-47b371f6a931' User entered 'None (0)'	System	28 Aug 2020 20:11:41
	System	28 Aug 2020 20:11:41

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:11:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-28T13:11:18', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '14f6bc8c-f51a-4cd0-992d-47b371f6a931' User entered 'None (0)'	System	28 Aug 2020 20:11:41
	System	28 Aug 2020 20:11:41

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:11:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-28T13:11:22', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '14f6bc8c-f51a-4cd0-992d-47b371f6a931' User entered 'None (0)'	System	28 Aug 2020 20:11:41
	System	28 Aug 2020 20:11:41

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-28T13:11:28', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '14f6bc8c-f51a-4cd0-992d-47b371f6a931'	System	28 Aug 2020 20:11:41
User entered 'No (N)'	System	28 Aug 2020 20:11:41

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:11:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-28T13:11:38', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '14f6bc8c-f51a-4cd0-992d-47b371f6a931' User entered '28 Aug 2020 13:11'	System	28 Aug 2020 20:11:41
	System	28 Aug 2020 20:11:41

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:11:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:11:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	27 Aug 2020 19:29:46
User entered 'Day 3'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:11:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-29T12:02:33', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '634641dc-f2d7-4cb0-8cfb-c144add06aeb' User entered 'None (0)'	System	29 Aug 2020 19:04:55
	System	29 Aug 2020 19:04:55

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:11:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-29T12:04:37', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '634641dc-f2d7-4cb0-8cfb-c144add06aeb' User entered 'None (0)'	System	29 Aug 2020 19:04:55
	System	29 Aug 2020 19:04:55

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:11:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-29T12:03:40', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '634641dc-f2d7-4cb0-8cfb-c144add06aeb' User entered 'None (0)'	System	29 Aug 2020 19:04:55
	System	29 Aug 2020 19:04:55

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:11:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-29T12:03:38', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '634641dc-f2d7-4cb0-8cfb-c144add06aeb' User entered 'None (0)'	System	29 Aug 2020 19:04:55
	System	29 Aug 2020 19:04:55

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:11:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-29T12:03:35', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '634641dc-f2d7-4cb0-8cfb-c144add06aeb' User entered 'None (0)'	System	29 Aug 2020 19:04:55
	System	29 Aug 2020 19:04:55

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:11:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-29T12:03:34', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '634641dc-f2d7-4cb0-8cfb-c144add06aeb' User entered 'None (0)'	System	29 Aug 2020 19:04:55
	System	29 Aug 2020 19:04:55

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-29T12:04:42', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '634641dc-f2d7-4cb0-8cfb-c144add06aeb' User entered 'No (N)'	System	29 Aug 2020 19:04:55
	System	29 Aug 2020 19:04:55

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:11:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-29T12:04:53', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '634641dc-f2d7-4cb0-8cfb-c144add06aeb' User entered '29 Aug 2020 12:04'	System	29 Aug 2020 19:04:55
	System	29 Aug 2020 19:04:55

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:11:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:11:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	27 Aug 2020 19:29:46
User entered 'Day 4'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:11:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-30T12:07:49', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '30dc5a0a-1d7e-47c3-b0dc-063962f14fb5' User entered 'None (0)'	System	30 Aug 2020 19:09:15
	System	30 Aug 2020 19:09:15

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:11:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-30T12:07:57', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '30dc5a0a-1d7e-47c3-b0dc-063962f14fb5' User entered 'None (0)'	System	30 Aug 2020 19:09:15
	System	30 Aug 2020 19:09:15

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:11:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-30T12:08:27', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '30dc5a0a-1d7e-47c3-b0dc-063962f14fb5'	System	30 Aug 2020 19:09:15
User entered 'No interference with activity (1)'	System	30 Aug 2020 19:09:15

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:11:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-30T12:08:33', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '30dc5a0a-1d7e-47c3-b0dc-063962f14fb5' User entered 'None (0)'	System	30 Aug 2020 19:09:15
	System	30 Aug 2020 19:09:15

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:11:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-30T12:08:38', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '30dc5a0a-1d7e-47c3-b0dc-063962f14fb5' User entered 'None (0)'	System	30 Aug 2020 19:09:15
	System	30 Aug 2020 19:09:15

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:11:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-30T12:08:43', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '30dc5a0a-1d7e-47c3-b0dc-063962f14fb5' User entered 'None (0)'	System	30 Aug 2020 19:09:15
	System	30 Aug 2020 19:09:15

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-30T12:08:48', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '30dc5a0a-1d7e-47c3-b0dc-063962f14fb5' User entered 'No (N)'	System	30 Aug 2020 19:09:15
	System	30 Aug 2020 19:09:15

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:11:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-30T12:09:14', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '30dc5a0a-1d7e-47c3-b0dc-063962f14fb5' User entered '30 Aug 2020 12:09'	System	30 Aug 2020 19:09:15
	System	30 Aug 2020 19:09:15

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:11:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:11:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	27 Aug 2020 19:29:46
User entered 'Day 5'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:11:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-31T12:14:42', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '6234f7ea-dd93-41db-b153-02857444f79c' User entered 'None (0)'	System	31 Aug 2020 19:22:00
	System	31 Aug 2020 19:22:00

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:11:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-31T12:14:48', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '6234f7ea-dd93-41db-b153-02857444f79c' User entered 'None (0)'	System	31 Aug 2020 19:22:00
	System	31 Aug 2020 19:22:00

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:11:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-31T12:14:51', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '6234f7ea-dd93-41db-b153-02857444f79c' User entered 'None (0)'	System	31 Aug 2020 19:22:00
	System	31 Aug 2020 19:22:00

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:11:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-31T12:14:55', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '6234f7ea-dd93-41db-b153-02857444f79c' User entered 'None (0)'	System	31 Aug 2020 19:22:00
	System	31 Aug 2020 19:22:00

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:11:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-31T12:14:59', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '6234f7ea-dd93-41db-b153-02857444f79c' User entered 'None (0)'	System	31 Aug 2020 19:22:00
	System	31 Aug 2020 19:22:00

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:11:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-31T12:15:02', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '6234f7ea-dd93-41db-b153-02857444f79c' User entered 'None (0)'	System	31 Aug 2020 19:22:00
	System	31 Aug 2020 19:22:00

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-31T12:15:06', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '6234f7ea-dd93-41db-b153-02857444f79c' User entered 'No (N)'	System	31 Aug 2020 19:22:00
	System	31 Aug 2020 19:22:00

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:11:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-08-31T12:15:10', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '6234f7ea-dd93-41db-b153-02857444f79c' User entered '31 Aug 2020 12:15'	System	31 Aug 2020 19:22:00
	System	31 Aug 2020 19:22:00

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:11:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:11:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	27 Aug 2020 19:29:46
User entered 'Day 6'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:11:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-09-01T12:45:18', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'f490589d-131a-4f55-b68d-54f134718390' User entered 'None (0)'	System	01 Sep 2020 19:45:48
	System	01 Sep 2020 19:45:48

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:11:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-09-01T12:45:22', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'f490589d-131a-4f55-b68d-54f134718390' User entered 'None (0)'	System	01 Sep 2020 19:45:48
	System	01 Sep 2020 19:45:48

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:11:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-09-01T12:45:26', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'f490589d-131a-4f55-b68d-54f134718390' User entered 'None (0)'	System	01 Sep 2020 19:45:48
	System	01 Sep 2020 19:45:48

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:11:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-09-01T12:45:31', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'f490589d-131a-4f55-b68d-54f134718390' User entered 'None (0)'	System	01 Sep 2020 19:45:48
	System	01 Sep 2020 19:45:48

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:11:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-09-01T12:45:34', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'f490589d-131a-4f55-b68d-54f134718390' User entered 'None (0)'	System	01 Sep 2020 19:45:48
	System	01 Sep 2020 19:45:48

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:11:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-09-01T12:45:37', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'f490589d-131a-4f55-b68d-54f134718390' User entered 'None (0)'	System	01 Sep 2020 19:45:48
	System	01 Sep 2020 19:45:48

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-09-01T12:45:40', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'f490589d-131a-4f55-b68d-54f134718390' User entered 'No (N)'	System	01 Sep 2020 19:45:48
	System	01 Sep 2020 19:45:48

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:11:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-09-01T12:45:45', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'f490589d-131a-4f55-b68d-54f134718390'	System	01 Sep 2020 19:45:48
User entered '01 Sep 2020 12:45'	System	01 Sep 2020 19:45:48

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:11:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:11:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	27 Aug 2020 19:29:46
User entered 'Day 7'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:11:47

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-09-02T13:45:38', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'adc60c2e-186b-4227-9f62-31c6a3b98e81' User entered 'None (0)'	System	02 Sep 2020 20:46:09
	System	02 Sep 2020 20:46:09

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:11:47

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-09-02T13:45:42', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'adc60c2e-186b-4227-9f62-31c6a3b98e81' User entered 'None (0)'	System	02 Sep 2020 20:46:09
	System	02 Sep 2020 20:46:09

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:11:47

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-09-02T13:45:45', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'adc60c2e-186b-4227-9f62-31c6a3b98e81' User entered 'None (0)'	System	02 Sep 2020 20:46:09
	System	02 Sep 2020 20:46:09

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:11:47

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-09-02T13:45:52', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'adc60c2e-186b-4227-9f62-31c6a3b98e81' User entered 'None (0)'	System	02 Sep 2020 20:46:09
	System	02 Sep 2020 20:46:09

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:11:47

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-09-02T13:45:55', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'adc60c2e-186b-4227-9f62-31c6a3b98e81' User entered 'None (0)'	System	02 Sep 2020 20:46:09
	System	02 Sep 2020 20:46:09

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:11:47

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-09-02T13:45:57', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'adc60c2e-186b-4227-9f62-31c6a3b98e81' User entered 'None (0)'	System	02 Sep 2020 20:46:09
	System	02 Sep 2020 20:46:09

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-09-02T13:46:00', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'adc60c2e-186b-4227-9f62-31c6a3b98e81' User entered 'No (N)'	System	02 Sep 2020 20:46:09
	System	02 Sep 2020 20:46:09

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:11:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-09-02T13:46:06', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'adc60c2e-186b-4227-9f62-31c6a3b98e81' User entered '02 Sep 2020 13:46'	System	02 Sep 2020 20:46:09
	System	02 Sep 2020 20:46:09

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:11:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 19:29:46

US3112030

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:11:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 19:29:46

US3112030

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:30:48
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	25 Sep 2020 23:25:19

US3112030

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:30:48
User entered '3 Sep 2020'	Karen Mylerberg (b) (4)	25 Sep 2020 23:25:19

US3112030

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:30:48
User entered 'Contact Made (CONTACT MADE)'	Karen Mylerberg (b) (4)	25 Sep 2020 23:25:19

US3112030

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:30:48
User entered empty.	Karen Mylerberg (b) (4)	25 Sep 2020 23:25:19

US3112030

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 21:30:48
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	25 Sep 2020 23:25:29

US3112030

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User entered 'I'	System	25 Sep 2020 23:25:29

US3112030

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	25 Sep 2020 23:25:49

US3112030

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '11 Sep 2020'	Karen Mylerberg (b) (4)	25 Sep 2020 23:25:49

US3112030

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered 'Contact Made (CONTACT MADE)'	Karen Mylerberg (b) (4)	25 Sep 2020 23:25:49

US3112030

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered empty.	Karen Mylerberg (b) (4)	25 Sep 2020 23:25:49

US3112030

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	25 Sep 2020 23:26:01

US3112030

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User entered 'I'	System	25 Sep 2020 23:26:01

US3112030

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered 'No (N)'	Karen Mylerberg (b) (4)	25 Sep 2020 23:26:23

US3112030

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered empty.	Karen Mylerberg (b) (4)	25 Sep 2020 23:26:23

US3112030

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered empty.	Karen Mylerberg (b) (4)	25 Sep 2020 23:26:23

US3112030

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered empty.	Karen Mylerberg (b) (4)	25 Sep 2020 23:26:23

US3112030

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	25 Sep 2020 23:26:30

US3112030

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User entered 'I'	System	25 Sep 2020 23:26:30

US3112030

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:11:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	25 Sep 2020 23:26:45

US3112030

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '25 Sep 2020'	Karen Mylerberg (b) (4)	25 Sep 2020 23:26:45

US3112030

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered 'Clinic (Clinic)'	Karen Mylerberg (b) (4)	25 Sep 2020 23:26:45

US3112030

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:11:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User entered 'VISIT3'	System	25 Sep 2020 23:26:45

US3112030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	25 Sep 2020 23:27:18

US3112030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '25 Sep 2020'	Karen Mylerberg (b) (4)	25 Sep 2020 23:27:18

US3112030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '13:23'	Karen Mylerberg (b) (4)	25 Sep 2020 23:27:18

US3112030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User entered '25 Sep 2020 13:23'	System	25 Sep 2020 23:27:18

US3112030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '98.4' F	Karen Mylerberg (b) (4)	25 Sep 2020 23:27:18

US3112030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered 'Oral (Oral)'	Karen Mylerberg (b) (4)	25 Sep 2020 23:27:18

US3112030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered empty.	Karen Mylerberg (b) (4)	25 Sep 2020 23:27:18

US3112030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '81'	Karen Mylerberg (b) (4)	25 Sep 2020 23:27:18

US3112030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User entered 'bpm'	System	25 Sep 2020 23:27:18

US3112030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '16'	Karen Mylerberg (b) (4)	25 Sep 2020 23:27:18

US3112030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User entered 'breaths/min'	System	25 Sep 2020 23:27:18

US3112030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '115'	Karen Mylerberg (b) (4)	25 Sep 2020 23:27:18

US3112030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User entered 'mmHg'	System	25 Sep 2020 23:27:18

US3112030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '061'	Karen Mylerberg (b) (4)	25 Sep 2020 23:27:18

US3112030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User entered 'mmHg'	System	25 Sep 2020 23:27:18

US3112030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42

US3112030

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42

US3112030

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:11:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered 'No (N)'	Karen Mylerberg (b) (4)	25 Sep 2020 23:27:28

US3112030

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:11:47

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered empty.	Karen Mylerberg (b) (4)	25 Sep 2020 23:27:28

US3112030

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:11:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	25 Sep 2020 23:27:45

US3112030

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:11:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '25 Sep 2020'	Karen Mylerberg (b) (4)	25 Sep 2020 23:27:45

US3112030

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:11:47

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered '13:45'	Karen Mylerberg (b) (4)	25 Sep 2020 23:27:45

US3112030

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:11:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User entered '25 Sep 2020 13:45'	System	25 Sep 2020 23:27:45

US3112030

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User signature succeeded.	Laurie Han-Conrad (b) (4)	12 Feb 2021 20:36:17
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	25 Sep 2020 23:27:53

US3112030

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:42
User entered 'I'	System	25 Sep 2020 23:27:53

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	30 Jul 2020 20:41:05
User entered 'Day 64'	System	30 Jul 2020 20:41:05

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-09-29T00:02:06', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'ddbcd835-5a63-41af-8d21-ed1c91332cac' User entered 'No (N)'	System	29 Sep 2020 07:02:39
	System	29 Sep 2020 07:02:39

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-09-29T00:02:22', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'ddbcd835-5a63-41af-8d21-ed1c91332cac'	System	29 Sep 2020 07:02:39
User entered 'No (N)'	System	29 Sep 2020 07:02:39

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-09-29T00:02:37', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'ddbcd835-5a63-41af-8d21-ed1c91332cac' User entered '29 Sep 2020 00:02:37'	System	29 Sep 2020 07:02:39
	System	29 Sep 2020 07:02:39

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	30 Jul 2020 20:41:05
User entered '29 Sep 2020 00:01'	System	30 Jul 2020 20:41:05

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	30 Jul 2020 20:41:05
User entered '03 Oct 2020 23:59'	System	30 Jul 2020 20:41:05

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	30 Jul 2020 20:41:05
User entered 'Day 71'	System	30 Jul 2020 20:41:05

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-10-08T12:00:57', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'cc66f417-3be6-4893-81c9-588312ffe230'	System	08 Oct 2020 19:01:28
User entered 'No (N)'	System	08 Oct 2020 19:01:28

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-10-08T12:01:09', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'cc66f417-3be6-4893-81c9-588312ffe230'	System	08 Oct 2020 19:01:28
User entered 'No (N)'	System	08 Oct 2020 19:01:28

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-10-08T12:01:21', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'cc66f417-3be6-4893-81c9-588312ffe230' User entered '08 Oct 2020 12:01:21'	System	08 Oct 2020 19:01:28
	System	08 Oct 2020 19:01:28

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	30 Jul 2020 20:41:05
User entered '06 Oct 2020 00:01'	System	30 Jul 2020 20:41:05

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	30 Jul 2020 20:41:05
User entered '10 Oct 2020 23:59'	System	30 Jul 2020 20:41:05

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	30 Jul 2020 20:41:05
User entered 'Day 78'	System	30 Jul 2020 20:41:05

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-10-13T15:13:44', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '780d564d-c468-42b2-8e35-537d1db501d4'	System	13 Oct 2020 22:13:58
User entered 'No (N)'	System	13 Oct 2020 22:13:58

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-10-13T15:13:50', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '780d564d-c468-42b2-8e35-537d1db501d4'	System	13 Oct 2020 22:13:58
User entered 'No (N)'	System	13 Oct 2020 22:13:58

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-10-13T15:13:54', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '780d564d-c468-42b2-8e35-537d1db501d4' User entered '13 Oct 2020 15:13:54'	System	13 Oct 2020 22:13:58
	System	13 Oct 2020 22:13:58

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	30 Jul 2020 20:41:05
User entered '13 Oct 2020 00:01'	System	30 Jul 2020 20:41:05

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	30 Jul 2020 20:41:05
User entered '17 Oct 2020 23:59'	System	30 Jul 2020 20:41:05

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	30 Jul 2020 20:41:05
User entered 'Day 92'	System	30 Jul 2020 20:41:05

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-10-29T21:17:16', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'daa2733e-9ebc-4239-81a9-332f6afb62c2'	System	30 Oct 2020 05:04:12
User entered 'Yes (Y)'	System	30 Oct 2020 05:04:12

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-10-29T21:17:31', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'daa2733e-9ebc-4239-81a9-332f6afb62c2'	System	30 Oct 2020 05:04:12
User entered 'No (N)'	System	30 Oct 2020 05:04:12

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[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)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-10-29T21:17:43', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'daa2733e-9ebc-4239-81a9-332f6afb62c2'	System	30 Oct 2020 05:04:12
User entered 'No (N)'	System	30 Oct 2020 05:04:12

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-10-29T22:03:17', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'daa2733e-9ebc-4239-81a9-332f6afb62c2'	System	30 Oct 2020 05:04:12
User entered 'No (N)'	System	30 Oct 2020 05:04:12

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-10-29T22:04:10', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'daa2733e-9ebc-4239-81a9-332f6afb62c2' User entered '29 Oct 2020 22:04:10'	System	30 Oct 2020 05:04:12
	System	30 Oct 2020 05:04:12

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	30 Jul 2020 20:41:05
User entered '27 Oct 2020 00:01'	System	30 Jul 2020 20:41:05

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	30 Jul 2020 20:41:05
User entered '31 Oct 2020 23:59'	System	30 Jul 2020 20:41:05

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	30 Jul 2020 20:41:05
User entered 'Day 99'	System	30 Jul 2020 20:41:05

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-11-03T00:15:20', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '598679de-7ca1-47b0-af9e-76a553183fa1' User entered 'Yes (Y)'	System	03 Nov 2020 08:16:21
	System	03 Nov 2020 08:16:21

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-11-03T00:15:32', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '598679de-7ca1-47b0-af9e-76a553183fa1'	System	03 Nov 2020 08:16:21
User entered 'No (N)'	System	03 Nov 2020 08:16:21

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-11-03T00:15:39', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '598679de-7ca1-47b0-af9e-76a553183fa1'	System	03 Nov 2020 08:16:21
User entered 'No (N)'	System	03 Nov 2020 08:16:21

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[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)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-11-03T00:15:51', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '598679de-7ca1-47b0-af9e-76a553183fa1' User entered 'No (N)'	System	03 Nov 2020 08:16:21
	System	03 Nov 2020 08:16:21

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-11-03T00:16:19', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '598679de-7ca1-47b0-af9e-76a553183fa1' User entered '03 Nov 2020 00:16:19'	System	03 Nov 2020 08:16:21
	System	03 Nov 2020 08:16:21

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	30 Jul 2020 20:41:05
User entered '03 Nov 2020 00:01'	System	30 Jul 2020 20:41:05

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	30 Jul 2020 20:41:05
User entered '07 Nov 2020 23:59'	System	30 Jul 2020 20:41:05

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	30 Jul 2020 20:41:05
User entered 'Day 106'	System	30 Jul 2020 20:41:05

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 02:34:11
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'per prog note in source PT reports having had two procedures on their back on the 26OCT2020 and 28OCT2020. both procedures were elective therapeutic procedures that had been non-responsive to previous therapeutic efforts. Operations were cervical vertebrae decompression of the c1-c7 vertebrae' (Site from DM).	Natalie Moy (b) (4)	30 Nov 2020 19:21:47
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 14:54:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-11-10T19:49:21', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'f9496b51-efc3-4830-90d3-87a724d6d64d'	System	11 Nov 2020 03:51:06

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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)
User entered 'Yes (Y)'	System	11 Nov 2020 03:51:06

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-11-10T19:49:31', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'f9496b51-efc3-4830-90d3-87a724d6d64d' User entered 'No (N)'	System	11 Nov 2020 03:51:06
	System	11 Nov 2020 03:51:06

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-11-10T19:49:37', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'f9496b51-efc3-4830-90d3-87a724d6d64d' User entered 'No (N)'	System	11 Nov 2020 03:51:06
	System	11 Nov 2020 03:51:06

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[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)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-11-10T19:50:08', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'f9496b51-efc3-4830-90d3-87a724d6d64d' User entered 'Yes (Y)'	System	11 Nov 2020 03:51:06
	System	11 Nov 2020 03:51:06

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Please 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)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-11-10T19:50:25', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'f9496b51-efc3-4830-90d3-87a724d6d64d'	System	11 Nov 2020 03:51:06
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	11 Nov 2020 03:51:06

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-11-10T19:50:56', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'f9496b51-efc3-4830-90d3-87a724d6d64d' User entered '10 Nov 2020 19:50:56'	System	11 Nov 2020 03:51:06
	System	11 Nov 2020 03:51:06

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	30 Jul 2020 20:41:05
User entered '10 Nov 2020 00:01'	System	30 Jul 2020 20:41:05

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	30 Jul 2020 20:41:05
User entered '14 Nov 2020 23:59'	System	30 Jul 2020 20:41:05

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	30 Jul 2020 20:41:05
User entered 'Day 113'	System	30 Jul 2020 20:41:05

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-11-17T01:37:28', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '02d7724a-b93a-4594-8121-e52602c87fae' User entered 'No (N)'	System	17 Nov 2020 09:37:48
	System	17 Nov 2020 09:37:48

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-11-17T01:37:36', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '02d7724a-b93a-4594-8121-e52602c87fae'	System	17 Nov 2020 09:37:48
User entered 'No (N)'	System	17 Nov 2020 09:37:48

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-11-17T01:37:46', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '02d7724a-b93a-4594-8121-e52602c87fae' User entered '17 Nov 2020 01:37:46'	System	17 Nov 2020 09:37:48
	System	17 Nov 2020 09:37:48

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	30 Jul 2020 20:41:05
User entered '17 Nov 2020 00:01'	System	30 Jul 2020 20:41:05

US3112030

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:32:13
Data entry locked.	System	30 Jul 2020 20:41:05
User entered '21 Nov 2020 23:59'	System	30 Jul 2020 20:41:05

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[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 (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-11-30T19:04:47', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '189b72be-7bfe-40ae-b8ae-92223d7d9949' User entered 'No (N)'	System	01 Dec 2020 03:05:21
	System	01 Dec 2020 03:05:21

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Have you been exposed to someone with 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 (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-11-30T19:04:57', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '189b72be-7bfe-40ae-b8ae-92223d7d9949' User entered 'No (N)'	System	01 Dec 2020 03:05:21
	System	01 Dec 2020 03:05:21

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-11-30T19:05:16', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '189b72be-7bfe-40ae-b8ae-92223d7d9949' User entered '30 Nov 2020 19:05:16'	System	01 Dec 2020 03:05:21
	System	01 Dec 2020 03:05:21

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[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 (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-12-07T14:40:43', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '819f36ca-5e1d-4e75-9099-49a2d6571fb3' User entered 'No (N)'	System	07 Dec 2020 22:40:57
	System	07 Dec 2020 22:40:57

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

Have you been exposed to someone with 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 (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-12-07T14:40:50', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '819f36ca-5e1d-4e75-9099-49a2d6571fb3'	System	07 Dec 2020 22:40:57
User entered 'No (N)'	System	07 Dec 2020 22:40:57

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-12-07T14:40:54', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '819f36ca-5e1d-4e75-9099-49a2d6571fb3' User entered '07 Dec 2020 14:40:54'	System	07 Dec 2020 22:40:57
	System	07 Dec 2020 22:40:57

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[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 (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-12-14T13:40:39', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '603c3002-ab42-44b5-a7ea-8c6d253a6c19' User entered 'No (N)'	System	14 Dec 2020 21:40:52
	System	14 Dec 2020 21:40:52

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

Have you been exposed to someone with 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 (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-12-14T13:40:45', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '603c3002-ab42-44b5-a7ea-8c6d253a6c19' User entered 'No (N)'	System	14 Dec 2020 21:40:52
	System	14 Dec 2020 21:40:52

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-12-14T13:40:50', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '603c3002-ab42-44b5-a7ea-8c6d253a6c19' User entered '14 Dec 2020 13:40:50'	System	14 Dec 2020 21:40:52
	System	14 Dec 2020 21:40:52

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[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 (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-12-20T18:32:33', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '6d4ab2ad-64f2-4544-a172-b989f2e0b5b7'	System	21 Dec 2020 02:32:48
User entered 'No (N)'	System	21 Dec 2020 02:32:48

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

Have you been exposed to someone with 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 (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-12-20T18:32:39', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '6d4ab2ad-64f2-4544-a172-b989f2e0b5b7' User entered 'No (N)'	System	21 Dec 2020 02:32:48
	System	21 Dec 2020 02:32:48

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-12-20T18:32:44', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '6d4ab2ad-64f2-4544-a172-b989f2e0b5b7' User entered '20 Dec 2020 18:32:44'	System	21 Dec 2020 02:32:48
	System	21 Dec 2020 02:32:48

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[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 (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-12-29T18:49:35', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'c2a855ff-c37f-4832-97e2-b2dd5eac669d' User entered 'No (N)'	System	30 Dec 2020 02:49:45
	System	30 Dec 2020 02:49:45

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

Have you been exposed to someone with 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 (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-12-29T18:49:39', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'c2a855ff-c37f-4832-97e2-b2dd5eac669d'	System	30 Dec 2020 02:49:45
User entered 'No (N)'	System	30 Dec 2020 02:49:45

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2020-12-29T18:49:42', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'c2a855ff-c37f-4832-97e2-b2dd5eac669d' User entered '29 Dec 2020 18:49:42'	System	30 Dec 2020 02:49:45
	System	30 Dec 2020 02:49:45

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[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 (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-01-05T18:22:20', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '3de24360-cc1e-4be7-8693-d0ec72916413' User entered 'No (N)'	System	06 Jan 2021 02:22:46
	System	06 Jan 2021 02:22:46

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Have you been exposed to someone with 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 (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-01-05T18:22:26', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '3de24360-cc1e-4be7-8693-d0ec72916413' User entered 'No (N)'	System	06 Jan 2021 02:22:46

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-01-05T18:22:38', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '3de24360-cc1e-4be7-8693-d0ec72916413' User entered '05 Jan 2021 18:22:38'	System	06 Jan 2021 02:22:46
	System	06 Jan 2021 02:22:46

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[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 (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-01-10T19:28:42', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '5f75a200-ba31-473d-ac28-b9b47d04ef81' User entered 'No (N)'	System	11 Jan 2021 03:29:09
	System	11 Jan 2021 03:29:09

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Have you been exposed to someone with 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 (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-01-10T19:29:00', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '5f75a200-ba31-473d-ac28-b9b47d04ef81' User entered 'No (N)'	System	11 Jan 2021 03:29:09

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-01-10T19:29:06', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '5f75a200-ba31-473d-ac28-b9b47d04ef81' User entered '10 Jan 2021 19:29:06'	System	11 Jan 2021 03:29:09
	System	11 Jan 2021 03:29:09

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[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 (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-01-18T12:13:39', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '21ccfa85-9f89-4fc8-a119-88c41e18c77c' User entered 'No (N)'	System	18 Jan 2021 20:14:07
	System	18 Jan 2021 20:14:07

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Have you been exposed to someone with 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 (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-01-18T12:13:50', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '21ccfa85-9f89-4fc8-a119-88c41e18c77c'	System	18 Jan 2021 20:14:07
User entered 'No (N)'	System	18 Jan 2021 20:14:07

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-01-18T12:14:01', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '21ccfa85-9f89-4fc8-a119-88c41e18c77c' User entered '18 Jan 2021 12:14:01'	System	18 Jan 2021 20:14:07
	System	18 Jan 2021 20:14:07

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[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 (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-01-25T12:16:37', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '7c38cc92-a01e-43d5-88b2-fc6e7d9153f5'	System	25 Jan 2021 20:26:53
User entered 'No (N)'	System	25 Jan 2021 20:26:53

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

Have you been exposed to someone with 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 (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-01-25T12:16:43', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '7c38cc92-a01e-43d5-88b2-fc6e7d9153f5'	System	25 Jan 2021 20:26:53
User entered 'No (N)'	System	25 Jan 2021 20:26:53

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-01-25T12:16:48', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '7c38cc92-a01e-43d5-88b2-fc6e7d9153f5' User entered '25 Jan 2021 12:16:48'	System	25 Jan 2021 20:26:53
	System	25 Jan 2021 20:26:53

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[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 (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-02-01T12:08:40', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '81ebda99-27d8-4552-a3c1-872e8948ce15'	System	01 Feb 2021 20:09:01
User entered 'No (N)'	System	01 Feb 2021 20:09:01

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Have you been exposed to someone with 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 (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-02-01T12:08:50', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '81ebda99-27d8-4552-a3c1-872e8948ce15'	System	01 Feb 2021 20:09:01
User entered 'No (N)'	System	01 Feb 2021 20:09:01

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-02-01T12:08:54', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '81ebda99-27d8-4552-a3c1-872e8948ce15' User entered '01 Feb 2021 12:08:54'	System	01 Feb 2021 20:09:01

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[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 (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-02-08T12:00:56', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '96e050b5-5944-4e2f-9ec7-996c1e1824c2' User entered 'No (N)'	System	08 Feb 2021 20:01:57
	System	08 Feb 2021 20:01:57

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

Have you been exposed to someone with 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 (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-02-08T12:01:01', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '96e050b5-5944-4e2f-9ec7-996c1e1824c2'	System	08 Feb 2021 20:01:57
User entered 'No (N)'	System	08 Feb 2021 20:01:57

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-02-08T12:01:06', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '96e050b5-5944-4e2f-9ec7-996c1e1824c2' User entered '08 Feb 2021 12:01:06'	System	08 Feb 2021 20:01:57
	System	08 Feb 2021 20:01:57

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[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 (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-02-13T01:01:06', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '0cf12efc-84e0-421c-97bb-2ed715f538b2'	System	13 Feb 2021 09:01:18
User entered 'No (N)'	System	13 Feb 2021 09:01:18

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Have you been exposed to someone with 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 (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-02-13T01:01:11', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '0cf12efc-84e0-421c-97bb-2ed715f538b2'	System	13 Feb 2021 09:01:18
User entered 'No (N)'	System	13 Feb 2021 09:01:18

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-02-13T01:01:15', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '0cf12efc-84e0-421c-97bb-2ed715f538b2' User entered '13 Feb 2021 01:01:15'	System	13 Feb 2021 09:01:18
	System	13 Feb 2021 09:01:18

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[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 (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-02-20T00:47:37', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '0b0c24d5-315e-4393-bcc8-a33029f2e421' User entered 'No (N)'	System	20 Feb 2021 08:47:49

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

Have you been exposed to someone with 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 (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-02-20T00:47:42', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '0b0c24d5-315e-4393-bcc8-a33029f2e421' User entered 'No (N)'	System	20 Feb 2021 08:47:49
	System	20 Feb 2021 08:47:49

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-02-20T00:47:47', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '0b0c24d5-315e-4393-bcc8-a33029f2e421' User entered '20 Feb 2021 00:47:47'	System	20 Feb 2021 08:47:49
	System	20 Feb 2021 08:47:49

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[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 (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-02-27T00:05:00-08:00', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '6fafa40b-c795-48ac-a679-c5a665221c2b'	System	27 Feb 2021 08:05:21
User entered 'No (N)'	System	27 Feb 2021 08:05:21

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

Have you been exposed to someone with 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 (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-02-27T00:05:12-08:00', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '6fafa40b-c795-48ac-a679-c5a665221c2b'	System	27 Feb 2021 08:05:21
User entered 'No (N)'	System	27 Feb 2021 08:05:21

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-02-27T00:05:17-08:00', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '6fafa40b-c795-48ac-a679-c5a665221c2b'	System	27 Feb 2021 08:05:21
User entered '27 Feb 2021 08:05:17'	System	27 Feb 2021 08:05:21

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[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 (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-03-08T10:11:19-08:00', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'f4c6856f-769f-4f72-97a7-d71b9f9b3fe5'	System	08 Mar 2021 18:16:59
User entered 'No (N)'	System	08 Mar 2021 18:16:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Have you been exposed to someone with 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 (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-03-08T10:11:22-08:00', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'f4c6856f-769f-4f72-97a7-d71b9f9b3fe5'	System	08 Mar 2021 18:16:59
User entered 'No (N)'	System	08 Mar 2021 18:16:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-03-08T10:11:26-08:00', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'f4c6856f-769f-4f72-97a7-d71b9f9b3fe5'	System	08 Mar 2021 18:16:59
User entered '08 Mar 2021 10:11:26'	System	08 Mar 2021 18:16:59

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[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 (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-03-15T12:31:25-07:00', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '9fc9de25-ed50-4c9a-9f5f-1128dbd0c7c2'	System	15 Mar 2021 19:31:43
User entered 'No (N)'	System	15 Mar 2021 19:31:43

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Have you been exposed to someone with 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 (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-03-15T12:31:34-07:00', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '9fc9de25-ed50-4c9a-9f5f-1128dbd0c7c2'	System	15 Mar 2021 19:31:43
User entered 'No (N)'	System	15 Mar 2021 19:31:43

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-03-15T12:31:39-07:00', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '9fc9de25-ed50-4c9a-9f5f-1128dbd0c7c2'	System	15 Mar 2021 19:31:43
User entered '15 Mar 2021 12:31:39'	System	15 Mar 2021 19:31:43

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[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 (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-03-20T00:02:59-07:00', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '76ec2e22-a23b-46d3-85a2-5f9b3972bd4c' User entered 'No (N)'	System	20 Mar 2021 07:03:17
	System	20 Mar 2021 07:03:17

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

Have you been exposed to someone with 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 (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-03-20T00:03:06-07:00', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '76ec2e22-a23b-46d3-85a2-5f9b3972bd4c' User entered 'No (N)'	System	20 Mar 2021 07:03:17
	System	20 Mar 2021 07:03:17

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-03-20T00:03:10-07:00', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '76ec2e22-a23b-46d3-85a2-5f9b3972bd4c' User entered '20 Mar 2021 00:03:10'	System	20 Mar 2021 07:03:17
	System	20 Mar 2021 07:03:17

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[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 (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-03-28T17:10:56-07:00', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '627fe021-0bd9-4b88-98da-66f32f6a42fa' User entered 'No (N)'	System	29 Mar 2021 00:12:34
	System	29 Mar 2021 00:12:34

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Have you been exposed to someone with 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 (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-03-28T17:11:09-07:00', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '627fe021-0bd9-4b88-98da-66f32f6a42fa'	System	29 Mar 2021 00:12:34
User entered 'No (N)'	System	29 Mar 2021 00:12:34

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-03-28T17:12:29-07:00', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '627fe021-0bd9-4b88-98da-66f32f6a42fa' User entered '28 Mar 2021 17:12:29'	System	29 Mar 2021 00:12:34
	System	29 Mar 2021 00:12:34

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[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 (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-04-03T17:27:27-07:00', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '8101def8-62bb-47a7-bb8f-073a0a28ef45'	System	06 Apr 2021 00:44:06
User entered 'No (N)'	System	06 Apr 2021 00:44:06

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Have you been exposed to someone with 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 (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-04-03T17:27:32-07:00', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '8101def8-62bb-47a7-bb8f-073a0a28ef45'	System	06 Apr 2021 00:44:06
User entered 'No (N)'	System	06 Apr 2021 00:44:06

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-04-03T17:27:37-07:00', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '8101def8-62bb-47a7-bb8f-073a0a28ef45'	System	06 Apr 2021 00:44:06
User entered '03 Apr 2021 17:27:37'	System	06 Apr 2021 00:44:06

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[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 (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-04-10T01:45:01-07:00', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'edac564e-63ca-4108-8210-08cc2236cc94'	System	10 Apr 2021 08:45:11
User entered 'No (N)'	System	10 Apr 2021 08:45:11

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

Have you been exposed to someone with 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 (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-04-10T01:45:05-07:00', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'edac564e-63ca-4108-8210-08cc2236cc94'	System	10 Apr 2021 08:45:11
User entered 'No (N)'	System	10 Apr 2021 08:45:11

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-04-10T01:45:09-07:00', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'edac564e-63ca-4108-8210-08cc2236cc94'	System	10 Apr 2021 08:45:11
User entered '10 Apr 2021 01:45:09'	System	10 Apr 2021 08:45:11

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[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 (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-04-18T13:36:08-07:00', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '0a6dbf10-ab32-4fe6-90a0-7326f77394e9'	System	18 Apr 2021 20:36:28
User entered 'No (N)'	System	18 Apr 2021 20:36:28

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

Have you been exposed to someone with 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 (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-04-18T13:36:20-07:00', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '0a6dbf10-ab32-4fe6-90a0-7326f77394e9'	System	18 Apr 2021 20:36:28
User entered 'No (N)'	System	18 Apr 2021 20:36:28

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-04-18T13:36:24-07:00', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '0a6dbf10-ab32-4fe6-90a0-7326f77394e9'	System	18 Apr 2021 20:36:28
User entered '18 Apr 2021 13:36:24'	System	18 Apr 2021 20:36:28

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[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 (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-04-24T00:25:49-07:00', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'bed0e815-910d-4b8a-a587-1e78390d7fd2'	System	29 Apr 2021 01:22:16
User entered 'No (N)'	System	29 Apr 2021 01:22:16

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Have you been exposed to someone with 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 (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-04-24T00:25:56-07:00', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'bed0e815-910d-4b8a-a587-1e78390d7fd2'	System	29 Apr 2021 01:22:16
User entered 'No (N)'	System	29 Apr 2021 01:22:16

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-04-24T00:25:59-07:00', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'bed0e815-910d-4b8a-a587-1e78390d7fd2'	System	29 Apr 2021 01:22:16
User entered '24 Apr 2021 00:25:59'	System	29 Apr 2021 01:22:16

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[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 (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-05-01T00:07:08-07:00', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'a4229958-3e07-4798-a9e1-1e516fd46f59'	System	01 May 2021 07:07:40
User entered 'No (N)'	System	01 May 2021 07:07:40

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Have you been exposed to someone with 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 (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-05-01T00:07:16-07:00', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'a4229958-3e07-4798-a9e1-1e516fd46f59'	System	01 May 2021 07:07:40
User entered 'No (N)'	System	01 May 2021 07:07:40

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-05-01T00:07:38-07:00', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: 'a4229958-3e07-4798-a9e1-1e516fd46f59'	System	01 May 2021 07:07:40
User entered '01 May 2021 00:07:38'	System	01 May 2021 07:07:40

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 10:38:39

US3112030

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:11:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:38:39
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 10:38:39

US3112030

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:11:47

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)	30 Apr 2021 10:53:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-03-08T10:12:18-08:00', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '67c1b7f1-2d2b-4f9d-afd9-f7212ea4463f' User entered 'No (N)'	System	08 Mar 2021 18:17:53
	System	08 Mar 2021 18:17:53

US3112030

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:11:47

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:53:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E79CC606-4C7F-4629-B6E2-D08B3D0F1426)', Time: '2021-03-08T10:12:31-08:00', User OID: 'PatientReportedOutcome (US3112030)', ODM File OID: '67c1b7f1-2d2b-4f9d-afd9-f7212ea4463f' User entered '08 Mar 2021 10:12:31'	System	08 Mar 2021 18:17:53
	System	08 Mar 2021 18:17:53

US3112030

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:40:25
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	(b) (4), (b) (6)	24 Oct 2020 12:48:15
User entered 'Yes (Y)' reason for change: Data Entry Error	Natalie Moy (b) (4)	21 Oct 2020 19:33:39
	(b) (4)	
Query 'Data is required. Please complete.' answered with 'call not made yet, mistake ' (Site from System).	Natalie Moy (b) (4)	20 Oct 2020 23:25:52
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 23:25:42
User entered empty; reason for change Data Entry Error	Natalie Moy (b) (4)	20 Oct 2020 23:25:42
	(b) (4)	
User entered 'Yes (Y)'	Natalie Moy (b) (4)	20 Oct 2020 23:24:45
	(b) (4)	

US3112030

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:40:25
User entered '21 Oct 2020' reason for change: Data Entry Error	Natalie Moy (b) (4)	21 Oct 2020 19:33:39
User entered empty; reason for change Data Entry Error	Natalie Moy (b) (4)	20 Oct 2020 23:25:42
User entered '20 Oct 2020'	Natalie Moy (b) (4)	20 Oct 2020 23:24:45

US3112030

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:40:25
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	Natalie Moy (b) (4)	21 Oct 2020 19:33:39
User entered empty; reason for change Data Entry Error	Natalie Moy (b) (4)	20 Oct 2020 23:25:42
User entered 'Contact Made (CONTACT MADE)'	Natalie Moy (b) (4)	20 Oct 2020 23:24:45

US3112030

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:40:25
User entered empty.	Natalie Moy (b) (4)	20 Oct 2020 23:24:45

US3112030

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User signature succeeded.	Laurie Han-Conrad (b) (4)	05 Mar 2021 19:40:25
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	(b) (4), (b) (6)	24 Oct 2020 12:48:34
User entered 'Yes (Y)' reason for change: Data Entry Error	Natalie Moy (b) (4)	21 Oct 2020 19:33:44
	(b) (4)	
Query 'Data is required. Please complete.' answered with 'call not made yet, mistake ' (Site from System).	Natalie Moy (b) (4)	20 Oct 2020 23:26:06
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Oct 2020 23:25:58
User entered empty; reason for change Data Entry Error	Natalie Moy (b) (4)	20 Oct 2020 23:25:58
	(b) (4)	
User entered 'Yes (Y)'	Natalie Moy (b) (4)	20 Oct 2020 23:24:49
	(b) (4)	

US3112030

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 22:14:26
User entered '1'	System	21 Oct 2020 19:33:44
User entered empty.	System	20 Oct 2020 23:25:58
User entered '1'	System	20 Oct 2020 23:24:49

US3112030

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:32:31
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	24 Nov 2020 22:55:37

US3112030

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:32:31
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '24 Nov 2020'	Matthew Musikanth (b) (4)	24 Nov 2020 22:55:37

US3112030

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:32:31
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Contact Made (CONTACT MADE)'	Matthew Musikanth (b) (4)	24 Nov 2020 22:55:37

US3112030

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:32:31
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	24 Nov 2020 22:55:37

US3112030

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:32:31
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	24 Nov 2020 22:55:42

US3112030

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:32:31
User entered 'I'	System	24 Nov 2020 22:55:42

US3112030

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:32:31
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	23 Dec 2020 22:47:16

US3112030

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:32:31
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '23 Dec 2020'	Karen Mylerberg (b) (4)	23 Dec 2020 22:47:16

US3112030

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:32:31
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Contact Made (CONTACT MADE)'	Karen Mylerberg (b) (4)	23 Dec 2020 22:47:16

US3112030

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:32:31
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Karen Mylerberg (b) (4)	23 Dec 2020 22:47:16

US3112030

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:32:31
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Yes (Y)'	Karen Mylerberg (b) (4)	23 Dec 2020 22:47:21

US3112030

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:32:31
User entered 'I'	System	23 Dec 2020 22:47:21

US3112030

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:32:31
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:27
User entered 'Yes (Y)'	Brenda Grande (b) (4)	26 Jan 2021 00:43:27

US3112030

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:32:31
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:27
User entered '25 Jan 2021'	Brenda Grande (b) (4)	26 Jan 2021 00:43:27

US3112030

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:32:31
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:27
User entered 'Contact Made (CONTACT MADE)'	Brenda Grande (b) (4)	26 Jan 2021 00:43:27

US3112030

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:32:31
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:27
User entered empty.	Brenda Grande (b) (4)	26 Jan 2021 00:43:27

US3112030

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:32:31
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Yes (Y)'	Brenda Grande (b) (4)	26 Jan 2021 00:43:12

US3112030

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:32:31
User entered 'I'	System	26 Jan 2021 00:43:12

US3112030

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:11:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:32:31
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:27
User entered 'Yes (Y)'	Natalie Moy (b) (4)	22 Feb 2021 23:33:57

US3112030

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:11:47

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:32:31
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:27
User closed query 'Per GCL Lab Recon: Immuno: Sample dated 22 FEB2021 is recorded under Visit 04 Day 209 visit in PPD GCL, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate.Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 10:04:19
Query 'Per GCL Lab Recon: Immuno: Sample dated 22 FEB2021 is recorded under Visit 04 Day 209 visit in PPD GCL, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate.Thank you.' answered with ' date has been entered into edc ' (Site from DM).	Brenda Grande (b) (4)	09 Mar 2021 18:17:07
User opened query 'Per GCL Lab Recon: Immuno: Sample dated 22 FEB2021 is recorded under Visit 04 Day 209 visit in PPD GCL, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate.Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 17:55:38
User entered '22 Feb 2021'	Natalie Moy (b) (4)	22 Feb 2021 23:33:57

US3112030

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:11:47

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 12:32:31
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:27
User entered 'Clinic (Clinic)'	Natalie Moy (b) (4)	22 Feb 2021 23:33:57

US3112030

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:11:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:32:31
User entered 'VISIT4'	System	22 Feb 2021 23:33:57

US3112030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:32:31
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:27
User entered 'Yes (Y)'	Brenda Grande (b) (4)	29 Mar 2021 15:45:13

US3112030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:32:31
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:27
User entered '22 Feb 2021'	Brenda Grande (b) (4)	29 Mar 2021 15:45:13

US3112030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:32:31
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:27
User entered '13:08'	Brenda Grande (b) (4)	29 Mar 2021 15:45:13

US3112030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:32:31
User entered '22 Feb 2021 13:08'	System	29 Mar 2021 15:45:13

US3112030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:32:31
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:27
User entered '98.1' F	Brenda Grande (b) (4)	29 Mar 2021 15:45:13

US3112030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:32:31
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:27
User entered 'Oral (Oral)'	Brenda Grande (b) (4)	29 Mar 2021 15:45:13

US3112030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:32:31
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:27
User entered empty.	Brenda Grande (b) (4)	29 Mar 2021 15:45:13

US3112030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:32:31
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:27
User entered '61'	Brenda Grande (b) (4)	29 Mar 2021 15:45:13

US3112030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:32:31
User entered 'bpm'	System	29 Mar 2021 15:45:13

US3112030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:32:31
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:27
User entered '16'	Brenda Grande (b) (4)	29 Mar 2021 15:45:13

US3112030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:32:31
User entered 'breaths/min'	System	29 Mar 2021 15:45:13

US3112030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:32:31
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:27
User entered '134'	Brenda Grande (b) (4)	29 Mar 2021 15:45:13

US3112030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:32:31
User entered 'mmHg'	System	29 Mar 2021 15:45:13

US3112030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:32:31
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:27
User entered '69'	Brenda Grande (b) (4)	29 Mar 2021 15:45:13

US3112030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:32:31
User entered 'mmHg'	System	29 Mar 2021 15:45:13

US3112030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:32:31

US3112030

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:32:31

US3112030

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:11:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:32:31
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:27
User entered 'No (N)'	Natalie Moy (b) (4)	22 Feb 2021 23:34:04

US3112030

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:11:47

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:32:31
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:27
User entered empty.	Natalie Moy (b) (4)	22 Feb 2021 23:34:04

US3112030

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:11:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:32:31
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:27
User entered 'Yes (Y)'	Brenda Grande (b) (4)	08 Mar 2021 21:15:07

US3112030

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:11:47

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:32:31
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:27
User entered '22 Feb 2021'	Brenda Grande (b) (4)	08 Mar 2021 21:15:07

US3112030

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:11:47

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:32:31
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:27
User entered '13:20'	Brenda Grande (b) (4)	08 Mar 2021 21:15:07

US3112030

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:11:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:32:31
User entered '22 Feb 2021 13:20'	System	08 Mar 2021 21:15:07

US3112030

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:32:31
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:27
User entered 'Yes (Y)'	Natalie Moy (b) (4)	22 Feb 2021 23:34:08

US3112030

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:32:31
User entered 'I'	System	22 Feb 2021 23:34:08

US3112030

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:56:35
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:27
User entered 'Yes (Y)'	Brenda Grande (b) (4)	26 Mar 2021 15:42:06

US3112030

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:56:35
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:27
User entered '23 Mar 2021'	Brenda Grande (b) (4)	26 Mar 2021 15:42:06

US3112030

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:56:35
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:27
User entered 'Contact Made (CONTACT MADE)'	Brenda Grande (b) (4)	26 Mar 2021 15:42:06

US3112030

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:56:35
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:27
User entered empty.	Brenda Grande (b) (4)	26 Mar 2021 15:42:06

US3112030

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:56:35
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:27
User entered 'Yes (Y)'	Brenda Grande (b) (4)	26 Mar 2021 15:42:11

US3112030

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:56:35
User entered 'I'	System	26 Mar 2021 15:42:11

US3112030

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:31
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	23 Apr 2021 18:40:59

US3112030

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:31
User entered '23 Apr 2021'	Matthew Musikanth (b) (4)	23 Apr 2021 18:40:59

US3112030

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:31
User entered 'Contact Made (CONTACT MADE)'	Matthew Musikanth (b) (4)	23 Apr 2021 18:40:59

US3112030

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:31
User entered empty.	Matthew Musikanth	23 Apr 2021 18:40:59
	(b) (4)	

US3112030

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:31
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	23 Apr 2021 18:41:03

US3112030

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:47

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Apr 2021 18:41:03

US3112030

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

Form: Visit Date

Generated On: 09 Jun 2021 15:11:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 12JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded in the Patient Decision Visit / OL-D1 folder. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 10:45:21
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 12JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded in the Patient Decision Visit / OL-D1 folder. Please clarify and update as appropriate.' answered with 'updated thank you' (Site from DM).	Natalie Moy (b) (4)	11 Feb 2021 18:54:08
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 12JAN2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded in the Patient Decision Visit / OL-D1 folder. Please clarify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 15:47:09
User entered 'Yes (Y)'	Nicolle Mendez (b) (4)	20 Jan 2021 21:56:17

US3112030

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

Form: Visit Date

Generated On: 09 Jun 2021 15:11:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '12 Jan 2021'	Nicolle Mendez (b) (4)	20 Jan 2021 21:56:17

US3112030

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

Form: Visit Date

Generated On: 09 Jun 2021 15:11:47

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 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Clinic (Clinic)'	Nicolle Mendez (b) (4)	20 Jan 2021 21:56:17

US3112030

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

Form: Visit Date

Generated On: 09 Jun 2021 15:11:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User entered 'UNBLND_DECIDE'	System	20 Jan 2021 21:56:17

US3112030

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

Form: Unblinding

Generated On: 09 Jun 2021 15:11:47

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '12 Jan 2021'	Nicolle Mendez (b) (4)	20 Jan 2021 21:56:54

US3112030

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

Form: Unblinding

Generated On: 09 Jun 2021 15:11:47

[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 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 10:54:50

US3112030

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

Form: Unblinding

Generated On: 09 Jun 2021 15:11:47

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Yes (Y)'	Nicolle Mendez (b) (4)	20 Jan 2021 21:56:54

US3112030

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

Form: Unblinding

Generated On: 09 Jun 2021 15:11:47

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 10:54:50

US3112030

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

Form: Unblinding

Generated On: 09 Jun 2021 15:11:47

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '12 Jan 2021'	Nicolle Mendez (b) (4)	20 Jan 2021 21:56:54

US3112030

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

Form: Unblinding

Generated On: 09 Jun 2021 15:11:47

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Placebo (Placebo)'	Nicolle Mendez (b) (4)	20 Jan 2021 21:56:54

US3112030

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

Form: Unblinding

Generated On: 09 Jun 2021 15:11:47

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Placebo (Placebo)'	Nicolle Mendez (b) (4)	20 Jan 2021 21:56:54

US3112030

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

Form: Unblinding

Generated On: 09 Jun 2021 15:11:47

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Placebo (Placebo)'	Nicolle Mendez (b) (4)	20 Jan 2021 21:56:54

US3112030

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

Form: Unblinding

Generated On: 09 Jun 2021 15:11:47

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Yes (Y)'	Nicolle Mendez (b) (4)	20 Jan 2021 21:56:54

US3112030

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

Form: Unblinding

Generated On: 09 Jun 2021 15:11:47

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User entered '1'	System	20 Jan 2021 21:56:54

US3112030

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

Form: Unblinding

Generated On: 09 Jun 2021 15:11:47

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User entered 'I'	System	20 Jan 2021 21:56:54

US3112030

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:11:47

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered missing code ND - Not Done.	Natalie Moy (b) (4)	11 Feb 2021 18:55:25

US3112030

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:11:47

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered missing code ND - Not Done.	Natalie Moy (b) (4)	11 Feb 2021 18:55:25

US3112030

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:11:47

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User entered empty.	System	11 Feb 2021 18:55:25
DataPoint set to visible.	System	20 Jan 2021 21:56:54

US3112030

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:11:47

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered missing code ND - Not Done.	Natalie Moy (b) (4)	11 Feb 2021 18:55:25

US3112030

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:11:47

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered missing code ND - Not Done.	Natalie Moy (b) (4)	11 Feb 2021 18:55:25

US3112030

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:11:47

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User entered empty.	System	11 Feb 2021 18:55:25
DataPoint set to visible.	System	20 Jan 2021 21:56:54

US3112030

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User accepted default value 'Pre-Dose (PREDOSE)'	Natalie Moy (b) (4) (b) (4)	11 Feb 2021 18:55:25

US3112030

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Yes (Y)'	Natalie Moy (b) (4)	11 Feb 2021 18:55:25

US3112030

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '12 Jan 2021'	Natalie Moy (b) (4)	11 Feb 2021 18:55:25

US3112030

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '15:10'	Natalie Moy (b) (4)	11 Feb 2021 18:55:25

US3112030

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User entered '12 Jan 2021 15:10'	System	11 Feb 2021 18:55:25

US3112030

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '97.9' F	Natalie Moy (b) (4)	11 Feb 2021 18:55:25

US3112030

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Oral (Oral)'	Natalie Moy (b) (4)	11 Feb 2021 18:55:25

US3112030

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Natalie Moy (b) (4)	11 Feb 2021 18:55:25

US3112030

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '74'	Natalie Moy (b) (4)	11 Feb 2021 18:55:25

US3112030

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User entered 'bpm'	System	11 Feb 2021 18:55:25

US3112030

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '16'	Natalie Moy (b) (4)	11 Feb 2021 18:55:25

US3112030

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User entered 'breaths/min'	System	11 Feb 2021 18:55:25

US3112030

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '100'	Natalie Moy (b) (4)	11 Feb 2021 18:55:25

US3112030

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User entered 'mmHg'	System	11 Feb 2021 18:55:25

US3112030

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '68'	Natalie Moy (b) (4)	11 Feb 2021 18:55:25

US3112030

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User entered 'mmHg'	System	11 Feb 2021 18:55:25

US3112030

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:11:47

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered missing code ND - Not Done.	Natalie Moy (b) (4)	11 Feb 2021 18:55:25

US3112030

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:11:47

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered missing code ND - Not Done.	Natalie Moy (b) (4)	11 Feb 2021 18:55:25

US3112030

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:11:47

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User entered empty.	System	11 Feb 2021 18:55:25
DataPoint set to visible.	System	20 Jan 2021 21:56:54

US3112030

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User accepted default value 'Post-Dose (POSTDOSE)'	Natalie Moy (b) (4) (b) (4)	11 Feb 2021 18:55:25

US3112030

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Yes (Y)'	Natalie Moy (b) (4)	11 Feb 2021 18:55:25

US3112030

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '12 Jan 2021'	Natalie Moy (b) (4)	11 Feb 2021 18:55:25

US3112030

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '16:20'	Natalie Moy (b) (4)	11 Feb 2021 18:55:25

US3112030

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User entered '12 Jan 2021 16:20'	System	11 Feb 2021 18:55:25

US3112030

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '98' F	Natalie Moy (b) (4)	11 Feb 2021 18:55:25

US3112030

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Oral (Oral)'	Natalie Moy (b) (4)	11 Feb 2021 18:55:25

US3112030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Natalie Moy (b) (4)	11 Feb 2021 18:55:25

US3112030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '70'	Natalie Moy (b) (4)	11 Feb 2021 18:55:25

US3112030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User entered 'bpm'	System	11 Feb 2021 18:55:25

US3112030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '16'	Natalie Moy (b) (4)	11 Feb 2021 18:55:25

US3112030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User entered 'breaths/min'	System	11 Feb 2021 18:55:25

US3112030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '102'	Natalie Moy (b) (4)	11 Feb 2021 18:55:25

US3112030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User entered 'mmHg'	System	11 Feb 2021 18:55:25

US3112030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '62'	Natalie Moy (b) (4)	11 Feb 2021 18:55:25

US3112030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User entered 'mmHg'	System	11 Feb 2021 18:55:25

US3112030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:11:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Yes (Y)'	Natalie Moy (b) (4)	11 Feb 2021 18:55:33

US3112030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:11:47

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '12 Jan 2021'	Natalie Moy (b) (4)	11 Feb 2021 18:55:33

US3112030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:11:47

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Yes (Y)'	Natalie Moy (b) (4)	11 Feb 2021 18:55:52

US3112030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:11:47

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Natalie Moy (b) (4)	11 Feb 2021 18:55:52

US3112030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:11:47

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 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Natalie Moy (b) (4)	11 Feb 2021 18:55:52

US3112030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:11:47

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User entered 'mRNA-1273'	System	11 Feb 2021 18:55:52
DataPoint set to visible.	System	20 Jan 2021 21:56:54

US3112030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:11:47

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '12 Jan 2021'	Natalie Moy (b) (4)	11 Feb 2021 18:55:52

US3112030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:11:47

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '15:49'	Natalie Moy (b) (4)	11 Feb 2021 18:55:52

US3112030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:11:47

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User entered '12 Jan 2021 15:49'	System	11 Feb 2021 18:55:52

US3112030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:11:47

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Left Arm (LEFT ARM)'	Natalie Moy (b) (4)	11 Feb 2021 18:55:52

US3112030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:11:47

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User entered 'ONCE'	System	11 Feb 2021 18:55:52

US3112030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:11:47

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User entered 'INTRAMUSCULAR'	System	11 Feb 2021 18:55:52

US3112030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:11:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Yes (Y)'	Natalie Moy (b) (4)	11 Feb 2021 18:56:14

US3112030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:11:47

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '12 Jan 2021'	Natalie Moy (b) (4)	11 Feb 2021 18:56:14

US3112030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:11:47

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '15:20'	Natalie Moy (b) (4)	11 Feb 2021 18:56:14

US3112030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:11:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User entered '12 Jan 2021 15:20'	System	11 Feb 2021 18:56:14

US3112030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:11:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Yes (Y)'	Natalie Moy (b) (4)	11 Feb 2021 18:56:23

US3112030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:11:47

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '12 Jan 2021'	Natalie Moy (b) (4)	11 Feb 2021 18:56:23

US3112030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:11:47

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '15:14'	Natalie Moy (b) (4)	11 Feb 2021 18:56:23

US3112030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:11:47

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User entered '12 Jan 2021 15:14'	System	11 Feb 2021 18:56:23

US3112030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Yes (Y)'	Nicolle Mendez (b) (4)	20 Jan 2021 21:57:01

US3112030

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User entered 'I'	System	20 Jan 2021 21:57:01

US3112030

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:27
User entered 'Yes (Y)'	Nicolle Mendez (b) (4)	20 Jan 2021 21:57:17

US3112030

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:27
User entered '20 Jan 2021'	Nicolle Mendez (b) (4)	20 Jan 2021 21:57:17

US3112030

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:27
User entered 'Contact Made (CONTACT MADE)'	Nicolle Mendez (b) (4)	20 Jan 2021 21:57:17

US3112030

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:27
User entered empty.	Nicolle Mendez (b) (4)	20 Jan 2021 21:57:17

US3112030

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:27
User entered 'Yes (Y)'	Nicolle Mendez (b) (4)	20 Jan 2021 21:57:22

US3112030

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User entered 'I'	System	20 Jan 2021 21:57:22

US3112030

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:47

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User entered '1'	System	20 Jan 2021 21:57:22
DataPoint set to visible.	System	20 Jan 2021 21:57:22

US3112030

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:11:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Yes (Y)'	Natalie Moy (b) (4)	17 Feb 2021 18:25:35

US3112030

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:11:47

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '16 Feb 2021'	Natalie Moy (b) (4)	17 Feb 2021 18:25:35

US3112030

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:11:47

[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 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Clinic (Clinic)'	Natalie Moy (b) (4)	17 Feb 2021 18:25:35

US3112030

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:11:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User entered 'OLD29'	System	17 Feb 2021 18:25:35

US3112030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User accepted default value 'Pre-Dose (PREDOSE)'	Natalie Moy (b) (4) (b) (4)	17 Feb 2021 18:26:28

US3112030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Yes (Y)'	Natalie Moy (b) (4)	17 Feb 2021 18:26:28

US3112030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '16 Feb 2021'	Natalie Moy (b) (4)	17 Feb 2021 18:26:28

US3112030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '15:14'	Natalie Moy (b) (4)	17 Feb 2021 18:26:28

US3112030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User entered '16 Feb 2021 15:14'	System	17 Feb 2021 18:26:28

US3112030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '98.1' F	Natalie Moy (b) (4)	17 Feb 2021 18:26:28

US3112030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Oral (Oral)'	Natalie Moy (b) (4)	17 Feb 2021 18:26:28

US3112030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Natalie Moy (b) (4)	17 Feb 2021 18:26:28

US3112030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '68'	Natalie Moy (b) (4)	17 Feb 2021 18:26:28

US3112030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User entered 'bpm'	System	17 Feb 2021 18:26:28

US3112030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '16'	Natalie Moy (b) (4)	17 Feb 2021 18:26:28

US3112030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User entered 'breaths/min'	System	17 Feb 2021 18:26:28

US3112030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '120'	Natalie Moy (b) (4)	17 Feb 2021 18:26:28

US3112030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User entered 'mmHg'	System	17 Feb 2021 18:26:28

US3112030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '60'	Natalie Moy (b) (4)	17 Feb 2021 18:26:28

US3112030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:11:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User entered 'mmHg'	System	17 Feb 2021 18:26:28

US3112030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User accepted default value 'Post-Dose (POSTDOSE)'	Natalie Moy (b) (4) (b) (4)	17 Feb 2021 18:26:28

US3112030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Yes (Y)'	Natalie Moy (b) (4)	17 Feb 2021 18:26:28

US3112030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '16 Feb 2021'	Natalie Moy (b) (4)	17 Feb 2021 18:26:28

US3112030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '16:36'	Natalie Moy (b) (4)	17 Feb 2021 18:26:28

US3112030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User entered '16 Feb 2021 16:36'	System	17 Feb 2021 18:26:28

US3112030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '98.6' F	Natalie Moy (b) (4)	17 Feb 2021 18:26:28

US3112030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Oral (Oral)'	Natalie Moy (b) (4)	17 Feb 2021 18:26:28

US3112030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Natalie Moy (b) (4)	17 Feb 2021 18:26:28

US3112030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '74'	Natalie Moy (b) (4)	17 Feb 2021 18:26:28

US3112030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User entered 'bpm'	System	17 Feb 2021 18:26:28

US3112030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '16'	Natalie Moy (b) (4)	17 Feb 2021 18:26:28

US3112030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User entered 'breaths/min'	System	17 Feb 2021 18:26:28

US3112030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '116'	Natalie Moy (b) (4)	17 Feb 2021 18:26:28

US3112030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User entered 'mmHg'	System	17 Feb 2021 18:26:28

US3112030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '62'	Natalie Moy (b) (4)	17 Feb 2021 18:26:28

US3112030

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:11:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User entered 'mmHg'	System	17 Feb 2021 18:26:28

US3112030

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:11:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Yes (Y)'	Natalie Moy (b) (4)	17 Feb 2021 18:26:34

US3112030

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:11:47

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '16 Feb 2021'	Natalie Moy (b) (4)	17 Feb 2021 18:26:34

US3112030

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:11:47

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Yes (Y)'	Natalie Moy (b) (4)	17 Feb 2021 18:26:50

US3112030

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:11:47

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Natalie Moy (b) (4)	17 Feb 2021 18:26:50

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:11:47

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 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Natalie Moy (b) (4)	17 Feb 2021 18:26:50

US3112030

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:11:47

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User entered 'mRNA-1273'	System	17 Feb 2021 18:26:50
DataPoint set to visible.	System	20 Jan 2021 21:57:22

US3112030

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:11:47

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '16 Feb 2021'	Natalie Moy (b) (4)	17 Feb 2021 18:26:50

US3112030

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:11:47

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '16:05'	Natalie Moy (b) (4)	17 Feb 2021 18:26:50

US3112030

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:11:47

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User entered '16 Feb 2021 16:05'	System	17 Feb 2021 18:26:50

US3112030

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:11:47

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Left Arm (LEFT ARM)'	Natalie Moy (b) (4)	17 Feb 2021 18:26:50

US3112030

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:11:47

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User entered 'ONCE'	System	17 Feb 2021 18:26:50

US3112030

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:11:47

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User entered 'INTRAMUSCULAR'	System	17 Feb 2021 18:26:50

US3112030

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 17MAR2021 is reported under OL-D57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Corresponding Visit on Immunogenicity Assessment page' (Site from DM). Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 17MAR2021 is reported under OL-D57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Corresponding Visit on Immunogenicity Assessment page' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 11:19:27
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 17MAR2021 is reported under OL-D57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Corresponding Visit on Immunogenicity Assessment page' (Site from DM).	Brenda Grande (b) (4)	30 Mar 2021 16:48:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Mar 2021 11:42:14
	Natalie Moy (b) (4)	17 Feb 2021 18:27:22

US3112030

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User entered 'I'	System	17 Feb 2021 18:27:22

US3112030

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:27
User entered 'Yes (Y)'	Brenda Grande (b) (4)	08 Mar 2021 17:30:48

US3112030

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:27
User entered '23 Feb 2021'	Brenda Grande (b) (4)	08 Mar 2021 17:30:48

US3112030

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:27
User entered 'Contact Made (CONTACT MADE)'	Brenda Grande (b) (4)	08 Mar 2021 17:30:48

US3112030

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:11:47

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:27
User entered empty.	Brenda Grande (b) (4)	08 Mar 2021 17:30:48

US3112030

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:27
User entered 'Yes (Y)'	Brenda Grande (b) (4)	08 Mar 2021 17:30:56

US3112030

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:11:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User entered 'I'	System	08 Mar 2021 17:30:56

US3112030

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:11:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Yes (Y)'	Brenda Grande (b) (4)	30 Mar 2021 16:48:39

US3112030

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:11:47

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '17 Mar 2021'	Brenda Grande (b) (4)	30 Mar 2021 16:48:39

US3112030

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:11:47

[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 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Clinic (Clinic)'	Brenda Grande (b) (4)	30 Mar 2021 16:48:39

US3112030

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:11:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User entered 'OLD57'	System	30 Mar 2021 16:48:39

US3112030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Yes (Y)'	Brenda Grande (b) (4)	30 Mar 2021 16:49:03

US3112030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '17 Mar 2021'	Brenda Grande (b) (4)	30 Mar 2021 16:49:03

US3112030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '15:02'	Brenda Grande (b) (4)	30 Mar 2021 16:49:03

US3112030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User entered '17 Mar 2021 15:02'	System	30 Mar 2021 16:49:03

US3112030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '98.0' F	Brenda Grande (b) (4)	30 Mar 2021 16:49:03

US3112030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Oral (Oral)'	Brenda Grande (b) (4)	30 Mar 2021 16:49:03

US3112030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Brenda Grande (b) (4)	30 Mar 2021 16:49:03

US3112030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '59'	Brenda Grande (b) (4)	30 Mar 2021 16:49:03

US3112030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User entered 'bpm'	System	30 Mar 2021 16:49:03

US3112030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '16'	Brenda Grande (b) (4)	30 Mar 2021 16:49:03

US3112030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User entered 'breaths/min'	System	30 Mar 2021 16:49:03

US3112030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '128'	Brenda Grande (b) (4)	30 Mar 2021 16:49:03

US3112030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User entered 'mmHg'	System	30 Mar 2021 16:49:03

US3112030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '65'	Brenda Grande (b) (4)	30 Mar 2021 16:49:03

US3112030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User entered 'mmHg'	System	30 Mar 2021 16:49:03

US3112030

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:11:47

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11

US3112030

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:11:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Yes (Y)'	Brenda Grande (b) (4)	30 Mar 2021 16:49:12

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Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:11:47

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '17 Mar 2021'	Brenda Grande (b) (4)	30 Mar 2021 16:49:12

US3112030

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:11:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Yes (Y)'	Brenda Grande (b) (4)	30 Mar 2021 16:49:21

US3112030

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:11:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '17 Mar 2021'	Brenda Grande (b) (4)	30 Mar 2021 16:49:21

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:11:47

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '15:20'	Brenda Grande (b) (4)	30 Mar 2021 16:49:21

US3112030

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:11:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:04:11
User entered '17 Mar 2021 15:20'	System	30 Mar 2021 16:49:21

US3112030

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:11:47

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:44:46
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:21
User entered 'Yes (Y)'	Laurie Han-Conrad (b) (4)	06 Aug 2020 18:21:01

US3112030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:47

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:06

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:47

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:06
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Neurological signs and symptoms NEC, PT: Dizziness, LLT: Dizziness - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 18:50:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 18:50:09
Data point term sent to Coder	System	06 Aug 2020 18:22:28
User entered 'Dizziness'	Laurie Han-Conrad (b) (4)	06 Aug 2020 18:22:26

US3112030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:47

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:06
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered 'No (N)'	Laurie Han-Conrad (b) (4)	06 Aug 2020 18:22:26

US3112030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:47

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:06
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered 'No (N)'	Laurie Han-Conrad (b) (4)	06 Aug 2020 18:22:26

US3112030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:47

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:06
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User closed query 'Per CDM: a response is expected. Please provide' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 18:12:30
Query 'Per CDM: a response is expected. Please provide' answered with 'updated' (Site from DM).	Natalie Moy (b) (4)	12 Oct 2020 17:35:38
User entered 'No (N)'	Natalie Moy (b) (4)	12 Oct 2020 17:35:31
User opened query 'Per CDM: a response is expected. Please provide' (Site from DM).	(b) (4), (b) (6)	11 Oct 2020 20:38:55
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:24:17

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:06
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
Query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 17:23:13
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	27 Aug 2020 19:29:46
User entered '30 Jul 2020'	Laurie Han-Conrad (b) (4)	06 Aug 2020 18:22:26

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:47

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:06
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered '13:30'	Laurie Han-Conrad (b) (4)	06 Aug 2020 18:22:26

US3112030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:47

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:06
User entered '30 Jul 2020 13:30'	System	06 Aug 2020 18:22:26

US3112030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:06
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered 'No (N)'	Laurie Han-Conrad (b) (4)	06 Aug 2020 18:22:26

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:06
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered '30 Jul 2020'	Laurie Han-Conrad (b) (4)	06 Aug 2020 18:22:26

US3112030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:47

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:06
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered '14:10'	Laurie Han-Conrad (b) (4)	06 Aug 2020 18:22:26

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:47

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:06
User entered '30 Jul 2020 14:10'	System	06 Aug 2020 18:22:26

US3112030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:47

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:06
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered 'Grade 1/Mild (Grade 1/Mild)'	Laurie Han-Conrad (b) (4)	06 Aug 2020 18:22:26

US3112030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:47

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:06
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered 'No (N)'	Laurie Han-Conrad (b) (4)	06 Aug 2020 18:22:26

US3112030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:47

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:06
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered '0'	Laurie Han-Conrad (b) (4)	06 Aug 2020 18:22:26

US3112030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:47

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:06
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered '0'	Laurie Han-Conrad (b) (4)	06 Aug 2020 18:22:26

US3112030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:06
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered '0'	Laurie Han-Conrad (b) (4)	06 Aug 2020 18:22:26

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:47

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:06
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered empty.	Laurie Han-Conrad (b) (4)	06 Aug 2020 18:22:26

US3112030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:47

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:06
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered empty.	Laurie Han-Conrad (b) (4)	06 Aug 2020 18:22:26

US3112030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:47

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:06
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered empty.	Laurie Han-Conrad (b) (4)	06 Aug 2020 18:22:26

US3112030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:47

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:06
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered empty.	Laurie Han-Conrad (b) (4)	06 Aug 2020 18:22:26

US3112030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:06
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered '0'	Laurie Han-Conrad (b) (4)	06 Aug 2020 18:22:26

US3112030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:06
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered '0'	Laurie Han-Conrad (b) (4)	06 Aug 2020 18:22:26

US3112030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:47

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:06
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered '0'	Laurie Han-Conrad (b) (4)	06 Aug 2020 18:22:26

US3112030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:47

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:06
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered 'Not Related (NOT RELATED)'	Laurie Han-Conrad (b) (4)	06 Aug 2020 18:22:26

US3112030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:47

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:06
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User closed query 'Per CDM: per sponsor review, please confirm event is related to Study procedure or update accordingly' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 04:31:30
Query 'Per CDM: per sponsor review, please confirm event is related to Study procedure or update accordingly' answered with 'confirmed, related to study procedure' (Site from DM).	Natalie Moy (b) (4)	17 Nov 2020 19:07:26
User opened query 'Per CDM: per sponsor review, please confirm event is related to Study procedure or update accordingly' (Site from DM).	(b) (4), (b) (6)	15 Nov 2020 12:06:55
User entered 'Related (RELATED)'	Laurie Han-Conrad (b) (4)	06 Aug 2020 18:22:26

US3112030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:47

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:06
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered 'None (NONE)'	Laurie Han-Conrad (b) (4)	06 Aug 2020 18:22:26

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:47

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:06
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered 'I'	Laurie Han-Conrad (b) (4)	06 Aug 2020 18:22:26

US3112030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:47

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:06
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered '0'	Laurie Han-Conrad (b) (4)	06 Aug 2020 18:22:26

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:47

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:06
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered '0'	Laurie Han-Conrad (b) (4)	06 Aug 2020 18:22:26

US3112030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:47

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:06
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Laurie Han-Conrad (b) (4)	06 Aug 2020 18:22:26

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:47

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:06
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered empty.	Laurie Han-Conrad (b) (4)	06 Aug 2020 18:22:26

US3112030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:47

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:06
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered empty.	Laurie Han-Conrad (b) (4)	06 Aug 2020 18:22:26

US3112030

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:47

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:06
Amendment Manager: User entered '0'	System	21 Aug 2020 01:24:19
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:24:17

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:47

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:06
Amendment Manager: User entered '0'	System	21 Aug 2020 01:24:19
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:24:17

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:11:47

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:06
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:24:17

US3112030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:11:47

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 18:11:56
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:43:48
User entered	System	14 Jan 2021 16:53:59
'USA-US062-2021-mRNA-1273-P301000006'		
User entered 'New'	(b) (4), (b) (6)	14 Jan 2021 16:53:59

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:11:47

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:43:48
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Mononeuropathies, PT: Nerve compression, LLT: Pinched nerve - version MedDRA\\23.0.	Coder Import (b) (4)	14 Jan 2021 12:15:51
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	14 Jan 2021 12:15:51
	(b) (4)	
Data point term sent to Coder	System	13 Jan 2021 23:43:45
User entered 'Pinched Nerve secondary to surgical complication'	Matthew Musikanth	13 Jan 2021 23:43:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:11:47

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:43:48
User entered 'Yes (Y)'	Matthew Musikanth	13 Jan 2021 23:43:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:11:47

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:43:48
User entered 'No (N)'	Matthew Musikanth	13 Jan 2021 23:43:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:11:47

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:43:48
User entered 'No (N)'	Matthew Musikanth	13 Jan 2021 23:43:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:11:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:43:48
User entered '26 Oct 2020'	Matthew Musikanth	13 Jan 2021 23:43:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:11:47

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:43:48
User entered empty.	Matthew Musikanth	13 Jan 2021 23:43:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:11:47

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Jan 2021 23:43:41

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Folder: Adverse Events

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[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:50:30
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User closed query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 08:58:35
Query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' answered with 'updated' (Site from DM).	Brenda Grande (b) (4)	09 Mar 2021 18:43:47
DataPoint Un-verified.	Brenda Grande (b) (4)	09 Mar 2021 18:43:36
User entered 'No (N)' reason for change: Data Entry Error	Brenda Grande (b) (4)	09 Mar 2021 18:43:36
User opened query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 10:59:40
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:43:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Brenda Grande (b) (4)	10 Feb 2021 18:09:25
User entered 'No (N)'	Matthew Musikanth (b) (4)	13 Jan 2021 23:43:41

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:50:32
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
DataPoint Un-verified.	Brenda Grande (b) (4)	09 Mar 2021 18:43:36
User entered '28 Oct 2020' reason for change: Data Entry Error	Brenda Grande (b) (4)	09 Mar 2021 18:43:36
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:43:48
User closed query 'PV Query: Please remove the end date until the event has fully resolved. If end date is to remain, please update outcome to resolved with sequelae.' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 17:19:39
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	10 Feb 2021 18:09:25
Query 'PV Query: Please remove the end date until the event has fully resolved. If end date is to remain, please update outcome to resolved with sequelae.' answered with 'updated' (Site from Safety).	Brenda Grande (b) (4)	10 Feb 2021 18:09:11
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	10 Feb 2021 18:09:05
User entered empty; reason for change Data Entry Error	Brenda Grande (b) (4)	10 Feb 2021 18:09:05
User opened query 'PV Query: Please remove the end date until the event has fully resolved. If end date is to remain, please update outcome to resolved with sequelae.' (Site from Safety).	(b) (4), (b) (6)	02 Feb 2021 01:03:12
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4), (b) (6)	19 Jan 2021 13:53:58
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'Operation to correct pinched nerve was successful, patient is still in physical therapy to correct grip strength. PI wishes to denote corrective action but continued recovery of grip strength as not complete.' (Site from System).	Matthew Musikanth (b) (4)	13 Jan 2021 23:45:22

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	13 Jan 2021 23:44:03
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	13 Jan 2021 23:44:03
User entered '28 Oct 2020' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	13 Jan 2021 23:44:03
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	13 Jan 2021 23:43:41
User entered empty.	Matthew Musikanth (b) (4)	13 Jan 2021 23:43:41

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End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
	(b) (4), (b) (6)	10 Mar 2021 15:34:18
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated' (Site from Safety).	Brenda Grande (b) (4)	09 Mar 2021 18:43:54
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 15:05:53
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:43:48
User entered empty.	Matthew Musikanth (b) (4)	13 Jan 2021 23:43:41

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Jan 2021 23:43:41

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Folder: Adverse Events

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:43:48
User entered 'Grade 3/Severe (Grade 3/Severe)'	Matthew Musikanth	13 Jan 2021 23:43:41
	(b) (4)	

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:43:48
User entered 'Yes (Y)'	Matthew Musikanth	13 Jan 2021 23:43:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:43:48
User entered '0'	Matthew Musikanth	13 Jan 2021 23:43:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:43:48
User entered '0'	Matthew Musikanth	13 Jan 2021 23:43:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:43:48
User entered 'I'	Matthew Musikanth	13 Jan 2021 23:43:41
	(b) (4)	

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:43:48
User entered '26 Oct 2020'	Matthew Musikanth	13 Jan 2021 23:43:41
	(b) (4)	

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Generated On: 09 Jun 2021 15:11:47

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User closed query 'PV Query: Hospital discharge summary was not received. Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 19:40:42
Query 'PV Query: Hospital discharge summary was not received. Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Resent' (Site from Safety).	Matthew Musikanth (b) (4)	16 Mar 2021 17:49:27
User opened query 'PV Query: Hospital discharge summary was not received. Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 16:12:39
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:43:48
User entered '30 Oct 2020'	Matthew Musikanth (b) (4)	13 Jan 2021 23:43:41

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:43:48
User entered 'No (N)'	Matthew Musikanth	13 Jan 2021 23:43:41
	(b) (4)	

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:43:48
User entered empty.	Matthew Musikanth	13 Jan 2021 23:43:41
	(b) (4)	

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:43:48
User entered '0'	Matthew Musikanth	13 Jan 2021 23:43:41
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:43:48
User entered '0'	Matthew Musikanth	13 Jan 2021 23:43:41
	(b) (4)	

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:43:48
User entered '0'	Matthew Musikanth	13 Jan 2021 23:43:41
	(b) (4)	

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Form: Adverse Events (2)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:43:48
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth	13 Jan 2021 23:43:41
	(b) (4)	

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:43:48
User entered 'Not Related (NOT RELATED)'	Matthew Musikanth	13 Jan 2021 23:43:41
	(b) (4)	

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:43:48
User entered 'Not Applicable (NOT APPLICABLE)'	Matthew Musikanth	13 Jan 2021 23:43:41
	(b) (4)	

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:43:48
User entered '0'	Matthew Musikanth	13 Jan 2021 23:43:41
	(b) (4)	

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User closed query 'PV Query: Please confirm event start date (reported as 26 Oct 2020) as treatment medication cefazolin was listed with start date of 23 Oct 2020.' (Site from Safety).	(b) (4), (b) (6)	23 Feb 2021 18:11:51
Query 'PV Query: Please confirm event start date (reported as 26 Oct 2020) as treatment medication cefazolin was listed with start date of 23 Oct 2020.' answered with 'Pinched nerve SAE began on 26Oct2020, however the operation that the patient had that led to the SAE occurred on 23Oct2020 in which they had the above noted cefazolin. ' (Site from Safety).	Matthew Musikanth (b) (4)	22 Feb 2021 23:59:05
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 21:29:38
User opened query 'PV Query: Please confirm event start date (reported as 26 Oct 2020) as treatment medication cefazolin was listed with start date of 23 Oct 2020.' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 15:05:30
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:43:48
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'Medications updated' (Site from DM).	Matthew Musikanth (b) (4)	04 Feb 2021 18:07:48
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 10:29:36

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Matthew Musikanth (b) (4)	13 Jan 2021 23:43:41

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:43:48
User entered 'I'	Matthew Musikanth	13 Jan 2021 23:43:41
	(b) (4)	

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:31
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:50:20
Signature has been broken.	Matthew Musikanth (b) (4)	16 Apr 2021 18:47:42
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	16 Apr 2021 18:47:42
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
	(b) (4), (b) (6)	
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 15:34:22
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'updated' (Site from Safety).	Brenda Grande (b) (4)	09 Mar 2021 18:44:07
DataPoint Un-verified.	Brenda Grande (b) (4)	09 Mar 2021 18:43:36
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Brenda Grande (b) (4)	09 Mar 2021 18:43:36
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 15:06:21
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:43:48
User closed query 'PV Query: An end date is provided for the event. Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 19:30:33

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[Outcome](#)

Audit	User	Time (GMT)
Query 'PV Query: An end date is provided for the event. Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'Operation to correct pinched nerve was successful and therefor ended adverse event of pinched nerve, patient is still in physical therapy to correct grip strength. PI wishes to denote corrective action as end date but continued recovery of grip strength as not complete' (Site from Safety).	Matthew Musikanth (b) (4)	22 Jan 2021 18:55:47
User opened query 'PV Query: An end date is provided for the event. Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 16:36:02
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Matthew Musikanth (b) (4)	13 Jan 2021 23:43:41

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:31
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:50:18
DataPoint Un-verified.	Matthew Musikanth	16 Apr 2021 18:47:42
	(b) (4)	
Signature has been broken.	Matthew Musikanth	16 Apr 2021 18:47:42
	(b) (4)	
User entered 'Diminished Bilateral grip strength'	Matthew Musikanth	16 Apr 2021 18:47:42
reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:43:48
User entered empty.	Matthew Musikanth	13 Jan 2021 23:43:41
	(b) (4)	

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User closed query 'PV Query: Lab/diagnostic test results were not received. Please provide any relevant laboratory and diagnostic test results (with units and reference ranges if applicable). If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	17 Mar 2021 19:40:37
Query 'PV Query: Lab/diagnostic test results were not received. Please provide any relevant laboratory and diagnostic test results (with units and reference ranges if applicable). If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'Resent. ' (Site from Safety).	Matthew Musikanth (b) (4)	16 Mar 2021 17:49:22
User opened query 'PV Query: Lab/diagnostic test results were not received. Please provide any relevant laboratory and diagnostic test results (with units and reference ranges if applicable). If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 16:12:09
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:43:48
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 17:19:50

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Lab/diagnostic test results were not received. Please provide any relevant laboratory and diagnostic test results (with units and reference ranges if applicable). If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 17:19:47
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'medical records have been faxed' (Site from Safety).	Brenda Grande (b) (4)	10 Feb 2021 18:10:01
Query 'PV Query: Lab/diagnostic test results were not received. Please provide any relevant laboratory and diagnostic test results (with units and reference ranges if applicable). If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'medical records have been faxed' (Site from Safety).	Brenda Grande (b) (4)	10 Feb 2021 18:09:55
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Feb 2021 01:03:41
User opened query 'PV Query: Lab/diagnostic test results were not received. Please provide any relevant laboratory and diagnostic test results (with units and reference ranges if applicable). If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	02 Feb 2021 01:02:38

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	27 Jan 2021 14:50:41
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'results have been sent ' (Site from Safety).	Brenda Grande (b) (4)	26 Jan 2021 15:48:15
User closed query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE?' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 19:30:31
Query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE?' answered with 'Operation to correct pinched nerve was successful and therefor ended adverse event of pinched nerve, patient is still in physical therapy to correct grip strength. PI wishes to denote corrective action as end date but continued recovery of grip strength as not complete' (Site from Safety).	Matthew Musikanth (b) (4)	22 Jan 2021 18:56:40
User opened query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE?' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 16:35:50
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 16:35:38

US3112030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:11:47

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Patient underwent elected cervical decompression resulting in complications. Pending medical records'	Matthew Musikanth (b) (4)	13 Jan 2021 23:43:41

US3112030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:11:47

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Jan 2021 23:43:41

US3112030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:11:47

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Jan 2021 23:43:41

US3112030

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:11:47

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Jan 2021 23:43:41

US3112030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:11:47

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
	(b) (4)	
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Abdominal and gastrointestinal injuries NEC, PT: Tooth fracture, LLT: Tooth fracture - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 18:35:53
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Feb 2021 18:35:53
	(b) (4)	
Data point term sent to Coder	System	26 Feb 2021 18:20:20
User entered 'cracked tooth'	Brenda Grande (b) (4)	26 Feb 2021 18:19:22
	(b) (4)	

US3112030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:11:47

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered 'Yes (Y)'	Brenda Grande (b) (4)	26 Feb 2021 18:19:22
	(b) (4)	

US3112030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:11:47

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered 'No (N)'	Brenda Grande (b) (4)	26 Feb 2021 18:19:22

US3112030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:11:47

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered 'No (N)'	Brenda Grande (b) (4)	26 Feb 2021 18:19:22
	(b) (4)	

US3112030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:11:47

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered '23 Feb 2021'	Brenda Grande (b) (4)	26 Feb 2021 18:19:22
	(b) (4)	

US3112030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:11:47

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered empty.	Brenda Grande (b) (4)	26 Feb 2021 18:19:22
	(b) (4)	

US3112030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:11:47

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 18:19:22

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered 'Yes (Y)'	Brenda Grande (b) (4)	26 Feb 2021 18:19:22
	(b) (4)	

US3112030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered empty.	Brenda Grande (b) (4)	26 Feb 2021 18:19:22
	(b) (4)	

US3112030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:11:47

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered empty.	Brenda Grande (b) (4)	26 Feb 2021 18:19:22
	(b) (4)	

US3112030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:11:47

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Feb 2021 18:19:22

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:11:47

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Brenda Grande (b) (4)	26 Feb 2021 18:19:22
	(b) (4)	

US3112030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:11:47

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered 'No (N)'	Brenda Grande (b) (4)	26 Feb 2021 18:19:22
	(b) (4)	

US3112030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:11:47

Death

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered '0'	Brenda Grande (b) (4)	26 Feb 2021 18:19:22
	(b) (4)	

US3112030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:11:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered '0'	Brenda Grande (b) (4)	26 Feb 2021 18:19:22
	(b) (4)	

US3112030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:11:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered '0'	Brenda Grande (b) (4)	26 Feb 2021 18:19:22
	(b) (4)	

US3112030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:11:47

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered empty.	Brenda Grande (b) (4)	26 Feb 2021 18:19:22
	(b) (4)	

US3112030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:11:47

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered empty.	Brenda Grande (b) (4)	26 Feb 2021 18:19:22
	(b) (4)	

US3112030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:11:47

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered empty.	Brenda Grande (b) (4)	26 Feb 2021 18:19:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:11:47

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered empty.	Brenda Grande (b) (4)	26 Feb 2021 18:19:22
	(b) (4)	

US3112030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:11:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered '0'	Brenda Grande (b) (4)	26 Feb 2021 18:19:22
	(b) (4)	

US3112030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:11:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered '0'	Brenda Grande (b) (4)	26 Feb 2021 18:19:22
	(b) (4)	

US3112030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:11:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered '0'	Brenda Grande (b) (4)	26 Feb 2021 18:19:22
	(b) (4)	

US3112030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:11:47

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered 'Not Related (NOT RELATED)'	Brenda Grande (b) (4)	26 Feb 2021 18:19:22

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:11:47

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered 'Not Related (NOT RELATED)'	Brenda Grande (b) (4)	26 Feb 2021 18:19:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:11:47

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered 'None (NONE)'	Brenda Grande (b) (4)	26 Feb 2021 18:19:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:11:47

None

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered '1'	Brenda Grande (b) (4)	26 Feb 2021 18:19:22
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:11:47

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4) [REDACTED]	19 Mar 2021 20:16:15
User entered '0'	Brenda Grande (b) (4) [REDACTED]	26 Feb 2021 18:19:22

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:11:47

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered '0'	Brenda Grande (b) (4)	26 Feb 2021 18:19:22
	(b) (4)	

US3112030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:11:47

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Brenda Grande (b) (4)	26 Feb 2021 18:19:34
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Brenda Grande (b) (4)	26 Feb 2021 18:19:22

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:11:47

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered empty.	Brenda Grande (b) (4)	26 Feb 2021 18:19:22
	(b) (4)	

US3112030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:11:47

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered empty.	Brenda Grande (b) (4)	26 Feb 2021 18:19:22
	(b) (4)	

US3112030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:11:47

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Feb 2021 18:19:22

US3112030

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:11:47

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Feb 2021 18:19:22

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:11:47

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:12

US3112030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:11:47

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:12
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Rhinitis, LLT: Rhinitis infective - version MedDRA\23.0.	Coder Import (b) (4)	06 Apr 2021 13:42:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	06 Apr 2021 13:42:51
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User closed query 'Per DM CLR: Please review and update AE term to reflect specific type of RHINITIS (Allergic or Infective). Please reconcile with the ConMed eCRF so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 04:19:44
Query 'Per DM CLR: Please review and update AE term to reflect specific type of RHINITIS (Allergic or Infective). Please reconcile with the ConMed eCRF so there is an appropriate match. ' answered with 'updated' (Site from DM).	Brenda Grande (b) (4)	26 Mar 2021 17:14:12
Data point term sent to Coder	System	26 Mar 2021 17:13:40
Coding entries removed.	Brenda Grande (b) (4)	26 Mar 2021 17:13:15
Signature has been broken.	Brenda Grande (b) (4)	26 Mar 2021 17:13:15
User entered 'RHINITIS due to Infective' reason for change: Data Entry Error	Brenda Grande (b) (4)	26 Mar 2021 17:13:15
User opened query 'Per DM CLR: Please review and update AE term to reflect specific type of RHINITIS (Allergic or Infective). Please reconcile with the ConMed eCRF so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	21 Mar 2021 03:14:14
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Rhinitis, LLT: Rhinitis - version MedDRA\23.0.	Coder Import (b) (4)	05 Mar 2021 16:52:55

US3112030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:11:47

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	05 Mar 2021 16:52:55
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	05 Mar 2021 16:52:34
User entered 'rhinitis'	Brenda Grande (b) (4)	05 Mar 2021 16:52:09
	(b) (4)	

US3112030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:11:47

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:12
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered 'Yes (Y)'	Brenda Grande (b) (4)	05 Mar 2021 16:52:09

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:11:47

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:12
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered 'No (N)'	Brenda Grande (b) (4)	05 Mar 2021 16:52:09

US3112030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:11:47

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:12
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered 'No (N)'	Brenda Grande (b) (4)	05 Mar 2021 16:52:09

US3112030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:11:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:12
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered '26 Oct 2020'	Brenda Grande (b) (4)	05 Mar 2021 16:52:09

US3112030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:11:47

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:12
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered empty.	Brenda Grande (b) (4)	05 Mar 2021 16:52:09

US3112030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:11:47

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:12
User entered empty.	System	05 Mar 2021 16:52:09

US3112030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:12
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered 'No (N)'	Brenda Grande (b) (4)	05 Mar 2021 16:52:09

US3112030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:12
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered '30 Oct 2020'	Brenda Grande (b) (4)	05 Mar 2021 16:52:09

US3112030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:11:47

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:12
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered empty.	Brenda Grande (b) (4)	05 Mar 2021 16:52:09

US3112030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:11:47

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:12
User entered empty.	System	05 Mar 2021 16:52:09

US3112030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:11:47

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:12
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered 'Grade 1/Mild (Grade 1/Mild)'	Brenda Grande (b) (4)	05 Mar 2021 16:52:09

US3112030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:11:47

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:12
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered 'No (N)'	Brenda Grande (b) (4)	05 Mar 2021 16:52:09

US3112030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:11:47

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:12
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered '0'	Brenda Grande (b) (4)	05 Mar 2021 16:52:09

US3112030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:11:47

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:12
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered '0'	Brenda Grande (b) (4)	05 Mar 2021 16:52:09

US3112030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:11:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:12
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered '0'	Brenda Grande (b) (4)	05 Mar 2021 16:52:09

US3112030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:11:47

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:12
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered empty.	Brenda Grande (b) (4)	05 Mar 2021 16:52:09

US3112030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:11:47

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:12
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered empty.	Brenda Grande (b) (4)	05 Mar 2021 16:52:09

US3112030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:11:47

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:12
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered empty.	Brenda Grande (b) (4)	05 Mar 2021 16:52:09

US3112030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:11:47

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:12
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered empty.	Brenda Grande (b) (4)	05 Mar 2021 16:52:09

US3112030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:11:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:12
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered '0'	Brenda Grande (b) (4)	05 Mar 2021 16:52:09

US3112030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:11:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:12
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered '0'	Brenda Grande (b) (4)	05 Mar 2021 16:52:09

US3112030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:11:47

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:12
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered '0'	Brenda Grande (b) (4)	05 Mar 2021 16:52:09

US3112030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:11:47

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:12
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered 'Not Related (NOT RELATED)'	Brenda Grande (b) (4)	05 Mar 2021 16:52:09

US3112030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:11:47

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:12
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered 'Not Related (NOT RELATED)'	Brenda Grande (b) (4)	05 Mar 2021 16:52:09

US3112030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:11:47

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:12
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered 'None (NONE)'	Brenda Grande (b) (4)	05 Mar 2021 16:52:09

US3112030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:11:47

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:12
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered '0'	Brenda Grande (b) (4)	05 Mar 2021 16:52:09

US3112030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:11:47

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:12
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered 'I'	Brenda Grande (b) (4)	05 Mar 2021 16:52:09

US3112030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:11:47

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:12
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered '0'	Brenda Grande (b) (4)	05 Mar 2021 16:52:09

US3112030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:11:47

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:12
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Brenda Grande (b) (4)	05 Mar 2021 16:52:09

US3112030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:11:47

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:12
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered empty.	Brenda Grande (b) (4)	05 Mar 2021 16:52:09

US3112030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:11:47

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:12
User signature succeeded.	Todd Simmons (b) (4)	19 Mar 2021 20:16:15
User entered empty.	Brenda Grande (b) (4)	05 Mar 2021 16:52:09

US3112030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:11:47

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:12
User entered '0'	System	05 Mar 2021 16:52:09

US3112030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:11:47

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:12
User entered 'I'	System	05 Mar 2021 16:52:09

US3112030

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:11:47

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:28:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:11:47

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:44:46
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:45:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	01 Sep 2020 18:06:57
User entered 'No (N)'	Karen Mylerberg (b) (4)	01 Aug 2020 00:56:18

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:11:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 10:26:41
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 10:26:41
	(b) (4)	
Data point term sent to Coder	System	01 Sep 2020 18:08:43
User entered 'Gabapentin'	Matthew Musikanth	01 Sep 2020 18:08:34
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:08:34

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
Query 'Per DM CLR: Please update the indication to reflect the location of PERIPHERAL SENSORY NEUROPATHY. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.	(b) (4), (b) (6)	24 Nov 2020 12:31:02
' canceled (Site from DM).		
User opened query 'Per DM CLR: Please update the indication to reflect the location of PERIPHERAL SENSORY NEUROPATHY. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.	(b) (4), (b) (6)	28 Oct 2020 09:43:41
' (Site from DM).		
User entered 'Peripheral Sensory Neuropathy'	Matthew Musikanth (b) (4)	01 Sep 2020 18:08:34

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '800'	Matthew Musikanth (b) (4)	01 Sep 2020 18:08:34

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:08:34

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	01 Sep 2020 18:08:34

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'twice daily (BID)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:08:34

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:11:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	01 Sep 2020 18:08:34

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:08:34

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	01 Sep 2020 18:08:34

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:11:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '02 Sep 2014'	Matthew Musikanth (b) (4)	01 Sep 2020 18:08:34

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '0'	Matthew Musikanth (b) (4)	01 Sep 2020 18:08:34

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:08:34

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	01 Sep 2020 18:08:34
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 18:08:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Sep 2020 18:08:42
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	01 Sep 2020 18:08:42
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 18:08:34
User entered empty.	Matthew Musikanth (b) (4)	01 Sep 2020 18:08:34

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	01 Sep 2020 18:08:34

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:08:34

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 18:08:34

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:11:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 10:26:41
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 10:26:41
	(b) (4)	
Data point term sent to Coder	System	01 Sep 2020 18:09:49
User entered 'Gabapentin'	Matthew Musikanth	01 Sep 2020 18:09:48
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 18:09:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Sep 2020 18:09:53
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	01 Sep 2020 18:09:53
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 18:09:48
User entered empty.	Matthew Musikanth (b) (4)	01 Sep 2020 18:09:48

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
Query 'Per DM CLR: Please update the indication to reflect the location of PERIPHERAL SENSORY NEUROPATHY. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate' canceled (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 12:31:06
User opened query 'Per DM CLR: Please update the indication to reflect the location of PERIPHERAL SENSORY NEUROPATHY. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 09:45:10
User entered 'Peripheral Sensory Nephropathy'	Matthew Musikanth (b) (4)	01 Sep 2020 18:09:48

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '1600'	Matthew Musikanth (b) (4)	01 Sep 2020 18:09:48

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:09:48

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	01 Sep 2020 18:09:48

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'other (OTHER)'	Matthew Musikanth	01 Sep 2020 18:09:48
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:11:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'QHS'	Matthew Musikanth (b) (4)	01 Sep 2020 18:09:48

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:09:48

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	01 Sep 2020 18:09:48
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:11:47

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '02 Sep 2014'	Matthew Musikanth (b) (4)	01 Sep 2020 18:09:48

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '0'	Matthew Musikanth (b) (4)	01 Sep 2020 18:09:48

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:09:48

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	01 Sep 2020 18:09:48
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:09:48

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 18:09:48

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 18:09:48

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 18:09:48

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:11:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN CALCIUM, PRODUCTSYNONYM: CRESTOR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 18:11:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 18:11:45
Data point term sent to Coder	System	01 Sep 2020 18:10:53
User entered 'Crestor'	Matthew Musikanth (b) (4)	01 Sep 2020 18:10:45

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:10:45

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Hyperlipidemia'	Matthew Musikanth	01 Sep 2020 18:10:45
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '20'	Matthew Musikanth (b) (4)	01 Sep 2020 18:10:45

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:10:45

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	01 Sep 2020 18:10:45

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'once daily (QD)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:10:45

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:11:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	01 Sep 2020 18:10:45

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:10:45

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	01 Sep 2020 18:10:45
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:11:47

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '16 Jan 2019'	Matthew Musikanth (b) (4)	01 Sep 2020 18:10:45

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '0'	Matthew Musikanth (b) (4)	01 Sep 2020 18:10:45

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:10:45

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	01 Sep 2020 18:10:45
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:10:45

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:10:45

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:10:45

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 18:10:45

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:11:47

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
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)	01 Sep 2020 18:13:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 18:13:43
Data point term sent to Coder	System	01 Sep 2020 18:12:58
User entered 'Aspirin'	Matthew Musikanth (b) (4)	01 Sep 2020 18:12:02

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:12:02

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Cardiac Prophylaxis'	Matthew Musikanth (b) (4)	01 Sep 2020 18:12:02

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '81'	Matthew Musikanth (b) (4)	01 Sep 2020 18:12:02

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:12:02

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	01 Sep 2020 18:12:02

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'once daily (QD)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:12:02

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:11:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	01 Sep 2020 18:12:02

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:12:02

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	01 Sep 2020 18:12:02
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:11:47

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '09 Apr 2020'	Matthew Musikanth	01 Sep 2020 18:12:02
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:11:47

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '0'	Matthew Musikanth (b) (4)	01 Sep 2020 18:12:02

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:12:02

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	01 Sep 2020 18:12:02
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:12:02

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:12:02

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:12:02

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 18:12:02

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:11:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: IPRATROPIUM BROMIDE;SALBUTAMOL SULFATE, PRODUCTSYNONYM: IPRATROPIUM/ALBUTEROL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 22:12:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 22:12:40
Data point term sent to Coder	System	01 Sep 2020 18:13:59
User entered 'Albuterol/ Ipratropium'	Matthew Musikanth (b) (4)	01 Sep 2020 18:13:30

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth	01 Sep 2020 18:13:30
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Asthma'	Matthew Musikanth	01 Sep 2020 18:13:30
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 16:49:27
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'Dependent on asthmatic symptoms ' (Site from DM).	Natalie Moy (b) (4)	06 Oct 2020 16:29:14
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 09:56:14
User entered '100/200'	Matthew Musikanth (b) (4)	01 Sep 2020 18:13:30

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'ug (ug)' reason for change: Data Entry Error	Natalie Moy (b) (4)	06 Oct 2020 16:27:24
User entered 'Other (OTHER)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:13:30

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User closed query ' Per DM CLR: Please review Dose unit "Other" specified as "MCG" as there is an available option for "ug" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate.' (Site from DM). Query '	(b) (4), (b) (6)	09 Oct 2020 16:49:23
Per DM CLR: Please review Dose unit "Other" specified as "MCG" as there is an available option for "ug" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate.' answered with 'changed to microgram (ug) from (mcg) ' (Site from DM).	Natalie Moy (b) (4)	06 Oct 2020 16:28:03
User entered empty; reason for change Data Entry Error	(b) (4)	06 Oct 2020 16:27:24
User opened query ' Per DM CLR: Please review Dose unit "Other" specified as "MCG" as there is an available option for "ug" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate.' (Site from DM). User entered 'MCG'	(b) (4), (b) (6)	02 Oct 2020 09:56:09
	Matthew Musikanth (b) (4)	01 Sep 2020 18:13:30

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'four times daily (QID)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:13:30

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:11:47

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	01 Sep 2020 18:13:30

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Matthew Musikanth (b) (4)	01 Sep 2020 18:13:30

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	01 Sep 2020 18:13:30
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:11:47

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '04 May 2017'	Matthew Musikanth (b) (4)	01 Sep 2020 18:13:30

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:11:47

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '0'	Matthew Musikanth (b) (4)	01 Sep 2020 18:13:30

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:13:30

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	01 Sep 2020 18:13:30
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:13:30

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	01 Sep 2020 18:13:30

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:13:30

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 18:13:30

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:11:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS USED IN ERECTILE DYSFUNCTION, PRODUCT: SILDENAFIL, PRODUCTSYNONYM: VIAGRA [SILDENAFIL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 18:15:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 18:15:50
Data point term sent to Coder	System	01 Sep 2020 18:15:02
User entered 'Viagra'	Matthew Musikanth (b) (4)	01 Sep 2020 18:14:26

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:14:26

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Erectile Dysfunction'	Matthew Musikanth (b) (4)	01 Sep 2020 18:14:26

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '100'	Matthew Musikanth (b) (4)	01 Sep 2020 18:14:26

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:14:26

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	01 Sep 2020 18:14:26

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'as needed (PRN)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:14:26

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:11:47

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	01 Sep 2020 18:14:26
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:14:26

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	01 Sep 2020 18:14:26
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:11:47

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'un UNK 2010'	Matthew Musikanth (b) (4)	01 Sep 2020 18:14:26

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:11:47

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '0'	Matthew Musikanth (b) (4)	01 Sep 2020 18:14:26

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:14:26

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	01 Sep 2020 18:14:26
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:14:26

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 18:14:26

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 18:14:26

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 18:14:26

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:11:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
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 HUMAN, PRODUCTSYNONYM: HUMULIN-R - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Sep 2020 15:06:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Sep 2020 15:06:49
Data point term sent to Coder	System	01 Sep 2020 18:16:10
User entered 'Humulin R u500'	Matthew Musikanth (b) (4)	01 Sep 2020 18:16:00

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:16:00

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'DMII'	Matthew Musikanth (b) (4)	01 Sep 2020 18:16:00

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '20'	Matthew Musikanth (b) (4)	01 Sep 2020 18:16:00

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Other (OTHER)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:16:00

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'units'	Matthew Musikanth (b) (4)	01 Sep 2020 18:16:00

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'other (OTHER)'	Matthew Musikanth	01 Sep 2020 18:16:00
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:11:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'in the morning'	Matthew Musikanth	01 Sep 2020 18:16:00
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Subcutaneous (SUBCUTANEOUS)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:16:00

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	01 Sep 2020 18:16:00
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:11:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '14 Apr 2014'	Matthew Musikanth (b) (4)	01 Sep 2020 18:16:00

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '0'	Matthew Musikanth (b) (4)	01 Sep 2020 18:16:00

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:16:00

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	01 Sep 2020 18:16:00
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:16:00

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 18:16:00

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 18:16:00

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 18:16:00

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:11:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
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 HUMAN, PRODUCTSYNONYM: HUMULIN-R - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Sep 2020 15:06:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Sep 2020 15:06:49
Data point term sent to Coder	System	01 Sep 2020 18:17:11
User entered 'Humulin R u500'	Matthew Musikanth (b) (4)	01 Sep 2020 18:16:51

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth	01 Sep 2020 18:16:51
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'DMII'	Matthew Musikanth (b) (4)	01 Sep 2020 18:16:51

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '30'	Matthew Musikanth (b) (4)	01 Sep 2020 18:16:51

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Other (OTHER)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:16:51

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'units'	Matthew Musikanth (b) (4)	01 Sep 2020 18:16:51

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'other (OTHER)'	Matthew Musikanth	01 Sep 2020 18:16:51
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:11:47

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'mid day'	Matthew Musikanth	01 Sep 2020 18:16:51
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Subcutaneous (SUBCUTANEOUS)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:16:51

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	01 Sep 2020 18:16:51
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:11:47

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '14 Aug 2014'	Matthew Musikanth (b) (4)	01 Sep 2020 18:16:51

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:11:47

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '0'	Matthew Musikanth (b) (4)	01 Sep 2020 18:16:51

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:16:51

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	01 Sep 2020 18:16:51
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:16:51

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 18:16:51

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 18:16:51

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 18:16:51

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:11:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
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 HUMAN, PRODUCTSYNONYM: HUMULIN-R - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Sep 2020 15:06:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Sep 2020 15:06:50
Data point term sent to Coder	System	01 Sep 2020 18:18:14
User entered 'Humulin R u500'	Matthew Musikanth (b) (4)	01 Sep 2020 18:17:43

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:17:43

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'DMII'	Matthew Musikanth (b) (4)	01 Sep 2020 18:17:43

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '25'	Matthew Musikanth (b) (4)	01 Sep 2020 18:17:43

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Other (OTHER)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:17:43

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'units'	Matthew Musikanth (b) (4)	01 Sep 2020 18:17:43

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'other (OTHER)'	Matthew Musikanth	01 Sep 2020 18:17:43
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:11:47

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '9pm daily'	Matthew Musikanth (b) (4)	01 Sep 2020 18:17:43

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Subcutaneous (SUBCUTANEOUS)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:17:43

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	01 Sep 2020 18:17:43
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:11:47

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '14 Aug 2014'	Matthew Musikanth (b) (4)	01 Sep 2020 18:17:43

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '0'	Matthew Musikanth (b) (4)	01 Sep 2020 18:17:43

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:17:43

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	01 Sep 2020 18:17:43
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:17:43

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 18:17:43

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 18:17:43

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 18:17:43

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:11:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: COMBINATIONS OF ORAL BLOOD GLUCOSE LOWERING DRUGS, PRODUCT: METFORMIN HYDROCHLORIDE;SITAGLIPTIN, PRODUCTSYNONYM: JANUMET [METFORMIN HYDROCHLORIDE;SITAGLIPTIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 01:54:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 01:54:18
Data point term sent to Coder	System	01 Sep 2020 18:19:15
User entered 'Janumet'	Matthew Musikanth (b) (4)	01 Sep 2020 18:18:32

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:18:32

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'DMII'	Matthew Musikanth	01 Sep 2020 18:18:32
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '50/1000'	Matthew Musikanth (b) (4)	01 Sep 2020 18:18:32

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:18:32

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	01 Sep 2020 18:18:32
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'twice daily (BID)'	Matthew Musikanth	01 Sep 2020 18:18:32
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:11:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	01 Sep 2020 18:18:32
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:18:32

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	01 Sep 2020 18:18:32
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:11:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '16 Jun 2018'	Matthew Musikanth (b) (4)	01 Sep 2020 18:18:32

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:11:47

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '0'	Matthew Musikanth (b) (4)	01 Sep 2020 18:18:32

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:18:32

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	01 Sep 2020 18:18:32
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:18:32

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	01 Sep 2020 18:18:32

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:18:32

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 18:18:32

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:11:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 18:34:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 18:34:45
Data point term sent to Coder	System	01 Sep 2020 18:33:57
User entered 'Omeprazole'	Matthew Musikanth (b) (4)	01 Sep 2020 18:33:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:33:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'GERD'	Matthew Musikanth (b) (4)	01 Sep 2020 18:33:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '20'	Matthew Musikanth (b) (4)	01 Sep 2020 18:33:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:33:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	01 Sep 2020 18:33:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'once daily (QD)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:33:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:11:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	01 Sep 2020 18:33:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:33:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	01 Sep 2020 18:33:12
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:11:47

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '19 Oct 2012'	Matthew Musikanth (b) (4)	01 Sep 2020 18:33:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:11:47

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '0'	Matthew Musikanth (b) (4)	01 Sep 2020 18:33:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:33:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	01 Sep 2020 18:33:12
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:33:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:33:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:33:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 18:33:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:11:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS FOR URINARY FREQUENCY AND INCONTINENCE, PRODUCT: SOLIFENACIN SUCCINATE, PRODUCTSYNONYM: VESICARE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	01 Sep 2020 18:34:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	01 Sep 2020 18:34:50
Data point term sent to Coder	System	01 Sep 2020 18:33:59
User entered 'Vesicare'	Matthew Musikanth (b) (4)	01 Sep 2020 18:33:48

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:33:48

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 11:31:18
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'med hx updated' (Site from DM).	Karen Mylerberg (b) (4)	01 Oct 2020 15:26:00
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 04:50:07
User entered 'OAB'	Matthew Musikanth (b) (4)	01 Sep 2020 18:33:48

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '10'	Matthew Musikanth (b) (4)	01 Sep 2020 18:33:48

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:33:48

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	01 Sep 2020 18:33:48
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'once daily (QD)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:33:48

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:11:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	01 Sep 2020 18:33:48

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:33:48

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	01 Sep 2020 18:33:48

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:11:47

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '22 Dec 2018'	Matthew Musikanth (b) (4)	01 Sep 2020 18:33:48

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:11:47

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '0'	Matthew Musikanth (b) (4)	01 Sep 2020 18:33:48

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:33:48

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	01 Sep 2020 18:33:48
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:33:48

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:33:48

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:33:48

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 18:33:48

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:11:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:14:28
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
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)	01 Sep 2020 18:36:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 18:36:45
Data point term sent to Coder	System	01 Sep 2020 18:36:07
User entered 'Jardiance'	Matthew Musikanth (b) (4)	01 Sep 2020 18:35:05

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:14:28
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:35:05

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:14:28
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 11:31:38
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'med hx updated' (Site from DM).	Karen Mylerberg (b) (4)	01 Oct 2020 15:26:13
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 04:50:31
User entered 'DMII'	Matthew Musikanth (b) (4)	01 Sep 2020 18:35:05

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:14:28
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '10'	Matthew Musikanth (b) (4)	01 Sep 2020 18:35:05

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:14:28
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:35:05

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:14:28
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	01 Sep 2020 18:35:05

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:14:28
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'once daily (QD)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:35:05

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:11:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:14:28
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	01 Sep 2020 18:35:05

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:14:28
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:35:05

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:14:28
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	01 Sep 2020 18:35:05

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:11:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:14:28
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '27 Feb 2017'	Matthew Musikanth (b) (4)	01 Sep 2020 18:35:05

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:11:47

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:14:28
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '0'	Matthew Musikanth (b) (4)	01 Sep 2020 18:35:05

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:14:28
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:35:05

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:14:28
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '24 Aug 2020'	Matthew Musikanth (b) (4)	01 Sep 2020 18:35:05

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:14:28
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:35:05

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:14:28
User entered '1'	System	01 Sep 2020 18:35:05

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:14:28
User entered '1'	System	01 Sep 2020 18:35:05

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:14:28
User entered '804 (804)'	System	01 Sep 2020 18:35:05

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:11:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
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)	01 Sep 2020 18:36:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 18:36:46
Data point term sent to Coder	System	01 Sep 2020 18:36:08
User entered 'Jardiance'	Matthew Musikanth (b) (4)	01 Sep 2020 18:35:40

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:35:40

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'DMII'	Matthew Musikanth	01 Sep 2020 18:35:40
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User closed query 'Per DM CLR: this Con Med had dose increased on 25 AUG 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 12:37:48
Query 'Per DM CLR: this Con Med had dose increased on 25 AUG 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen.' answered with 'noticed raise in blood sugar prior to entry to study, spoke to pcp, who raised his dosage of jardiance ' (Site from DM).	Natalie Moy (b) (4)	21 Oct 2020 19:35:17
	(b) (4)	
User opened query 'Per DM CLR: this Con Med had dose increased on 25 AUG 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 20:16:18
User entered '25'	Matthew Musikanth (b) (4)	01 Sep 2020 18:35:40

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:35:40

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	01 Sep 2020 18:35:40

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'once daily (QD)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:35:40

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:11:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	01 Sep 2020 18:35:40

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:35:40

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	01 Sep 2020 18:35:40

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:11:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '25 Aug 2020'	Matthew Musikanth (b) (4)	01 Sep 2020 18:35:40

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:11:47

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '0'	Matthew Musikanth (b) (4)	01 Sep 2020 18:35:40

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:35:40

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	01 Sep 2020 18:35:40
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	01 Sep 2020 18:35:40

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:35:40

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:35:40

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 18:35:40

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:11:47

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:14:17
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
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 HUMAN, PRODUCTSYNONYM: HUMULIN R - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Oct 2020 06:54:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Oct 2020 06:54:45
Data point term sent to Coder	System	21 Oct 2020 19:37:30
User entered 'HUmulin R u500'	Natalie Moy (b) (4)	21 Oct 2020 19:37:05

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:14:17
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Natalie Moy (b) (4)	21 Oct 2020 19:37:05

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:14:17
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'DM 2'	Natalie Moy (b) (4)	21 Oct 2020 19:37:05

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:14:17
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '18'	Natalie Moy (b) (4)	21 Oct 2020 19:37:05

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:14:17
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Other (OTHER)'	Natalie Moy (b) (4)	21 Oct 2020 19:37:05

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:14:17
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'units'	Natalie Moy (b) (4)	21 Oct 2020 19:37:05

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:14:17
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	21 Oct 2020 19:37:13
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	21 Oct 2020 19:37:13
User entered 'once daily (QD)' reason for change: Data Entry Error	Natalie Moy (b) (4)	21 Oct 2020 19:37:13
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	21 Oct 2020 19:37:05
User entered 'once (ONCE)'	Natalie Moy (b) (4)	21 Oct 2020 19:37:05

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:11:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:14:17
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Natalie Moy (b) (4)	21 Oct 2020 19:37:05

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:14:17
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Oral (ORAL)'	Natalie Moy (b) (4)	21 Oct 2020 19:37:05

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:14:17
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Natalie Moy (b) (4)	21 Oct 2020 19:37:05

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:11:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:14:17
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '17 Oct 2020'	Natalie Moy (b) (4)	21 Oct 2020 19:37:05

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:14:17
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '0'	Natalie Moy (b) (4)	21 Oct 2020 19:37:05

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:14:17
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 19:37:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Oct 2020 19:37:17
User entered 'No (N)' reason for change: Data Entry Error	Natalie Moy (b) (4)	21 Oct 2020 19:37:17
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 19:37:05
User entered empty.	Natalie Moy (b) (4)	21 Oct 2020 19:37:05

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:14:17
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '19 Oct 2020'	Natalie Moy (b) (4)	21 Oct 2020 19:37:05

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:14:17
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Natalie Moy (b) (4)	21 Oct 2020 19:37:05

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:14:17
User entered '1'	System	21 Oct 2020 19:37:13
User entered empty.	System	21 Oct 2020 19:37:05

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:14:17
User entered '1'	System	21 Oct 2020 19:37:13
User entered empty.	System	21 Oct 2020 19:37:05

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:14:17
User entered '804 (804)'	System	21 Oct 2020 19:37:13
User entered empty.	System	21 Oct 2020 19:37:05

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:11:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: DRUGS USED IN ADDICTIVE DISORDERS, ATC: DRUGS USED IN NICOTINE DEPENDENCE, PRODUCT: VARENICLINE TARTRATE, PRODUCTSYNONYM: CHANTIX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 19:40:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 19:40:36
Data point term sent to Coder	System	21 Oct 2020 19:39:36
User entered 'chantix'	Natalie Moy (b) (4)	21 Oct 2020 19:38:46

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Natalie Moy (b) (4)	21 Oct 2020 19:38:46
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'smoking cessation aid'	Natalie Moy (b) (4)	21 Oct 2020 19:38:46
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '5'	Natalie Moy (b) (4)	21 Oct 2020 19:38:46
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'mg (mg)'	Natalie Moy (b) (4)	21 Oct 2020 19:38:46
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Natalie Moy (b) (4)	21 Oct 2020 19:38:46
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'once daily (QD)'	Natalie Moy (b) (4)	21 Oct 2020 19:38:46
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:11:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Natalie Moy (b) (4)	21 Oct 2020 19:38:46
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Oral (ORAL)'	Natalie Moy (b) (4)	21 Oct 2020 19:38:46
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Natalie Moy (b) (4)	21 Oct 2020 19:38:46
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:11:47

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '20 Oct 2020'	Natalie Moy (b) (4)	21 Oct 2020 19:38:46
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '0'	Natalie Moy (b) (4)	21 Oct 2020 19:38:46
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Yes (Y)'	Natalie Moy (b) (4)	21 Oct 2020 19:38:46
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Natalie Moy (b) (4)	21 Oct 2020 19:38:46
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Natalie Moy (b) (4)	21 Oct 2020 19:38:46
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 19:38:46

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 19:38:46

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 19:38:46

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:11:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:46:34
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFAZOLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 10:35:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 10:35:58
Data point term sent to Coder	System	03 Feb 2021 17:31:34
User entered 'Cefazolin'	Matthew Musikanth (b) (4)	03 Feb 2021 17:31:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:46:34
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 17:31:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:46:34
User entered 'Pinched Nerve'	Matthew Musikanth (b) (4)	03 Feb 2021 17:31:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:46:34
User entered '2'	Matthew Musikanth (b) (4)	03 Feb 2021 17:31:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:46:34
User entered 'g (g)'	Matthew Musikanth (b) (4)	03 Feb 2021 17:31:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:46:34
User entered empty.	Matthew Musikanth (b) (4)	03 Feb 2021 17:31:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:46:34
User entered 'once (ONCE)'	Matthew Musikanth (b) (4)	03 Feb 2021 17:31:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:11:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:46:34
User entered empty.	Matthew Musikanth (b) (4)	03 Feb 2021 17:31:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:46:34
User entered 'Intravenous (INTRAVENOUS)'	Matthew Musikanth (b) (4)	03 Feb 2021 17:31:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:46:34
User entered empty.	Matthew Musikanth (b) (4)	03 Feb 2021 17:31:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:11:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:46:34
User entered '23 Oct 2020'	Matthew Musikanth (b) (4)	03 Feb 2021 17:31:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:46:34
User entered '0'	Matthew Musikanth (b) (4)	03 Feb 2021 17:31:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:46:34
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 17:31:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:46:34
User entered '23 Oct 2020'	Matthew Musikanth (b) (4)	03 Feb 2021 17:31:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:50
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:46:34
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 17:31:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:50
User entered empty.	System	03 Feb 2021 17:31:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:50
User entered empty.	System	03 Feb 2021 17:31:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:50
User entered empty.	System	03 Feb 2021 17:31:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:11:47

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:45
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:47:06
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFAZOLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 10:35:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 10:35:58
Data point term sent to Coder	System	03 Feb 2021 17:56:02
Data point term sent to Coder	System	03 Feb 2021 17:49:57
User entered 'Cefazolin'	Matthew Musikanth (b) (4)	03 Feb 2021 17:49:06

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:45
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:47:06
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 17:49:06

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:45
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:47:06
User entered 'Pinched Nerve' reason for change:	Matthew Musikanth	03 Feb 2021 17:55:35
Data Entry Error	(b) (4)	
User entered '2'	Matthew Musikanth	03 Feb 2021 17:49:06
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:45
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:47:06
User entered '2'	Matthew Musikanth (b) (4)	03 Feb 2021 17:49:06

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:45
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:47:06
User entered 'g (g)'	Matthew Musikanth (b) (4)	03 Feb 2021 17:49:06

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:45
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:47:06
User entered empty.	Matthew Musikanth (b) (4)	03 Feb 2021 17:49:06

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:45
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:47:06
User entered 'once (ONCE)'	Matthew Musikanth (b) (4)	03 Feb 2021 17:49:06

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:11:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:45
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:47:06
User entered empty.	Matthew Musikanth (b) (4)	03 Feb 2021 17:49:06

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:45
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:47:06
User entered 'Intravenous (INTRAVENOUS)'	Matthew Musikanth (b) (4)	03 Feb 2021 17:49:06

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:45
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:47:06
User entered empty.	Matthew Musikanth (b) (4)	03 Feb 2021 17:49:06

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:11:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:45
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:47:06
User entered '26 Oct 2020'	Matthew Musikanth (b) (4)	03 Feb 2021 17:49:06

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:45
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:47:06
User entered '0'	Matthew Musikanth (b) (4)	03 Feb 2021 17:49:06

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:45
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:47:06
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 17:49:06

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:45
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:47:06
User entered '26 Oct 2020'	Matthew Musikanth (b) (4)	03 Feb 2021 17:49:06

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:45
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:47:06
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Feb 2021 17:55:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Feb 2021 17:55:35
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	03 Feb 2021 17:55:35
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Feb 2021 17:49:06
User entered empty.	Matthew Musikanth (b) (4)	03 Feb 2021 17:49:06

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:45
User entered empty.	System	03 Feb 2021 17:49:06

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:45
User entered empty.	System	03 Feb 2021 17:49:06

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:45
User entered empty.	System	03 Feb 2021 17:49:06

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:11:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:47:31
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFAZOLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 10:35:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 10:35:59
Data point term sent to Coder	System	03 Feb 2021 17:49:58
User entered 'Cefazolin'	Matthew Musikanth (b) (4)	03 Feb 2021 17:49:49

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:47:31
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 17:49:49

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:47:31
User entered 'Pinched nerve'	Matthew Musikanth (b) (4)	03 Feb 2021 17:49:49

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:47:31
User entered 'I'	Matthew Musikanth (b) (4)	03 Feb 2021 17:49:49

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:47:31
User entered 'g (g)'	Matthew Musikanth (b) (4)	03 Feb 2021 17:49:49

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:47:31
User entered empty.	Matthew Musikanth (b) (4)	03 Feb 2021 17:49:49

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:47:31
User entered 'once (ONCE)'	Matthew Musikanth (b) (4)	03 Feb 2021 17:49:49

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:11:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:47:31
User entered empty.	Matthew Musikanth (b) (4)	03 Feb 2021 17:49:49

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:47:31
User entered 'Intravenous (INTRAVENOUS)'	Matthew Musikanth (b) (4)	03 Feb 2021 17:49:49

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:47:31
User entered empty.	Matthew Musikanth (b) (4)	03 Feb 2021 17:49:49

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:11:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:47:31
User entered '26 Oct 2020'	Matthew Musikanth (b) (4)	03 Feb 2021 17:49:49

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:47:31
User entered '0'	Matthew Musikanth (b) (4)	03 Feb 2021 17:49:49

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:47:31
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 17:49:49

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:47:31
User entered '26 Oct 2020'	Matthew Musikanth (b) (4)	03 Feb 2021 17:49:49

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:04
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:47:31
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 17:49:49

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:04
User entered empty.	System	03 Feb 2021 17:49:49

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:04
User entered empty.	System	03 Feb 2021 17:49:49

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:04
User entered empty.	System	03 Feb 2021 17:49:49

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:11:47

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:09
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:48:28
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFAZOLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 10:35:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 10:35:57
Data point term sent to Coder	System	03 Feb 2021 19:09:06
Data point term sent to Coder	System	03 Feb 2021 17:55:02
User entered 'Cefazolin'	Matthew Musikanth (b) (4)	03 Feb 2021 17:54:17

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:09
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:48:28
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 17:54:17

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:09
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:48:28
User entered 'Pinched Nerve'	Matthew Musikanth (b) (4)	03 Feb 2021 17:54:17

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:09
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:48:28
User entered '2'	Matthew Musikanth (b) (4)	03 Feb 2021 17:54:17

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:09
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:48:28
User entered 'g (g)'	Matthew Musikanth (b) (4)	03 Feb 2021 17:54:17

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:09
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:48:28
User entered empty.	Matthew Musikanth (b) (4)	03 Feb 2021 17:54:17

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:09
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:48:28
User entered 'other (OTHER)'	Matthew Musikanth (b) (4)	03 Feb 2021 17:54:17

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:11:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:09
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:48:28
User entered 'q8hrs'	Matthew Musikanth (b) (4)	03 Feb 2021 17:54:17

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:09
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:48:28
User entered 'Other (OTHER)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	03 Feb 2021 19:08:41
User entered 'Intramuscular (INTRAMUSCULAR)'	Matthew Musikanth (b) (4)	03 Feb 2021 17:54:17

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:09
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:48:28
User entered 'Injection' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	03 Feb 2021 19:08:41
User entered empty.	Matthew Musikanth (b) (4)	03 Feb 2021 17:54:17

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:11:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:09
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:48:28
User entered '26 Oct 2020'	Matthew Musikanth (b) (4)	03 Feb 2021 17:54:17

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:09
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:48:28
User entered '0'	Matthew Musikanth (b) (4)	03 Feb 2021 17:54:17

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:09
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:48:28
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 17:54:17

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:09
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:22:39
User closed query 'Please clarify. Source indicates stop date of 27Oct2020. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	17 Feb 2021 23:22:37
Query 'Please clarify. Source indicates stop date of 27Oct2020. Please confirm and update as necessary.' answered with 'updated' (Site from CRA).	Matthew Musikanth (b) (4)	17 Feb 2021 23:13:38
DataPoint Un-verified.	Matthew Musikanth (b) (4)	17 Feb 2021 23:13:33
User entered '27 Oct 2020' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	17 Feb 2021 23:13:33
User opened query 'Please clarify. Source indicates stop date of 27Oct2020. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	17 Feb 2021 22:49:43
Query 'Please clarify. Source indicates stop date of 27Oct2020. Please confirm and update as necessary.' canceled (Site from CRA).	(b) (4), (b) (6)	17 Feb 2021 22:49:35
User opened query 'Please clarify. Source indicates stop date of 27Oct2020. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	17 Feb 2021 22:49:27
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:48:28
User entered '26 Oct 2020'	Matthew Musikanth (b) (4)	03 Feb 2021 17:54:17

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:09
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:48:28
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Feb 2021 17:55:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Feb 2021 17:55:14
User entered 'No (N)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	03 Feb 2021 17:55:14
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Feb 2021 17:54:17
User entered empty.	Matthew Musikanth (b) (4)	03 Feb 2021 17:54:17

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:09
User entered empty.	System	03 Feb 2021 17:54:17

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:09
User entered empty.	System	03 Feb 2021 17:54:17

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:09
User entered empty.	System	03 Feb 2021 17:54:17

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:11:47

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:16
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:50:19
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFAZOLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 10:35:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 10:35:58
Data point term sent to Coder	System	03 Feb 2021 19:11:07
Data point term sent to Coder	System	03 Feb 2021 17:55:02
User entered 'Cefazolin'	Matthew Musikanth (b) (4)	03 Feb 2021 17:54:59

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:16
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:50:19
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 17:54:59

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:16
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:50:19
User entered 'Pinched Nerve'	Matthew Musikanth (b) (4)	03 Feb 2021 17:54:59

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:16
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:50:19
User entered 'I'	Matthew Musikanth (b) (4)	03 Feb 2021 17:54:59

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:16
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:50:19
User entered 'g (g)'	Matthew Musikanth (b) (4)	03 Feb 2021 17:54:59

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:16
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:50:19
User entered empty.	Matthew Musikanth (b) (4)	03 Feb 2021 17:54:59

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:16
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:50:19
User entered 'other (OTHER)'	Matthew Musikanth (b) (4)	03 Feb 2021 17:54:59

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:11:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:16
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:50:19
User entered 'q8hrs'	Matthew Musikanth (b) (4)	03 Feb 2021 17:54:59

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:16
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:50:19
User entered 'Other (OTHER)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	03 Feb 2021 19:10:27
User entered 'Intramuscular (INTRAMUSCULAR)'	Matthew Musikanth (b) (4)	03 Feb 2021 17:54:59

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:16
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:50:19
User entered 'Injection' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	03 Feb 2021 19:10:27
User entered empty.	Matthew Musikanth (b) (4)	03 Feb 2021 17:54:59

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:11:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:16
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:50:19
User entered '27 Oct 2020'	Matthew Musikanth (b) (4)	03 Feb 2021 17:54:59

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:16
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:50:19
User entered '0'	Matthew Musikanth (b) (4)	03 Feb 2021 17:54:59

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:16
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:50:19
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 17:54:59

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:16
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:22:48
User closed query 'Please clarify. Source indicates stop date of 29Oct2020. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	17 Feb 2021 23:22:46
Query 'Please clarify. Source indicates stop date of 29Oct2020. Please confirm and update as necessary.' answered with 'updated' (Site from CRA).	Matthew Musikanth (b) (4)	17 Feb 2021 23:14:08
DataPoint Un-verified.	Matthew Musikanth (b) (4)	17 Feb 2021 23:14:02
User entered '29 Oct 2020' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	17 Feb 2021 23:14:02
User opened query 'Please clarify. Source indicates stop date of 29Oct2020. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	17 Feb 2021 22:50:47
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:50:19
User entered '27 Oct 2020'	Matthew Musikanth (b) (4)	03 Feb 2021 17:54:59

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:16
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:50:19
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 17:54:59

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:16
User entered empty.	System	03 Feb 2021 17:54:59

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:16
User entered empty.	System	03 Feb 2021 17:54:59

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:09:16
User entered empty.	System	03 Feb 2021 17:54:59

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:11:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: FERROUS SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Feb 2021 18:04:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Feb 2021 18:04:27
Data point term sent to Coder	System	03 Feb 2021 18:03:18
User entered 'Ferrous Sulfate'	Matthew Musikanth (b) (4)	03 Feb 2021 18:02:40

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 04:34:17
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'updated' (Site from DM).	Brenda Grande (b) (4)	05 Mar 2021 16:00:52
User entered 'Yes (Y)' reason for change: Data Entry Error	Brenda Grande (b) (4)	05 Mar 2021 16:00:45
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 04:38:31
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:02:40

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Supplement'	Matthew Musikanth (b) (4)	03 Feb 2021 18:02:40

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '325'	Matthew Musikanth (b) (4)	03 Feb 2021 18:02:40

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:02:40

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	03 Feb 2021 18:02:40

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'once daily (QD)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:02:40

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:11:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	03 Feb 2021 18:02:40

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:02:40

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	03 Feb 2021 18:02:40
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:11:47

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'un Jul 2020' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	04 Feb 2021 17:35:48
User entered '27 Oct 2020'	Matthew Musikanth (b) (4)	03 Feb 2021 18:02:40

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '0'	Matthew Musikanth (b) (4)	03 Feb 2021 18:02:40

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	04 Feb 2021 17:35:48
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:02:40

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty; reason for change Data Entry Error	Matthew Musikanth (b) (4)	04 Feb 2021 17:35:48
User entered '27 Oct 2020'	Matthew Musikanth (b) (4)	03 Feb 2021 18:02:40

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:02:40

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Feb 2021 18:02:40

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Feb 2021 18:02:40

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Feb 2021 18:02:40

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:11:47

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:19
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Feb 2021 18:05:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Feb 2021 18:05:33
Data point term sent to Coder	System	03 Feb 2021 18:04:19
User entered 'Flonase'	Matthew Musikanth (b) (4)	03 Feb 2021 18:03:47

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:19
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:03:47

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:19
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 04:35:10
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' answered with 'ae updated' (Site from DM).	Brenda Grande (b) (4)	05 Mar 2021 16:54:30
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 04:40:09
User entered 'Rhinitis'	Matthew Musikanth (b) (4)	03 Feb 2021 18:03:47

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:19
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '50'	Matthew Musikanth (b) (4)	03 Feb 2021 18:03:47

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:19
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Other (OTHER)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:03:47

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:19
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'mcg'	Matthew Musikanth (b) (4)	03 Feb 2021 18:03:47

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:19
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'as needed (PRN)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:03:47

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:11:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:19
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	03 Feb 2021 18:03:47

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:19
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Nasal (NASAL)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:03:47

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:19
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	03 Feb 2021 18:03:47

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:11:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:19
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '30 Oct 2020'	Matthew Musikanth (b) (4)	03 Feb 2021 18:03:47

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:19
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '0'	Matthew Musikanth (b) (4)	03 Feb 2021 18:03:47

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:19
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:03:47

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:19
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '30 Oct 2020'	Matthew Musikanth (b) (4)	03 Feb 2021 18:03:47

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:19
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:03:47

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:19
User entered empty.	System	03 Feb 2021 18:03:47

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:19
User entered empty.	System	03 Feb 2021 18:03:47

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:19
User entered empty.	System	03 Feb 2021 18:03:47

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:11:47

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:24
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: OTHER ANTIBACTERIALS, PRODUCT: BACITRACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Mar 2021 04:56:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Mar 2021 04:56:59
Data point term sent to Coder	System	05 Mar 2021 17:36:37
Coding entries removed.	Brenda Grande (b) (4)	05 Mar 2021 17:36:26
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: OTHER ANTIBACTERIALS, PRODUCT: BACITRACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Feb 2021 19:29:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Feb 2021 19:29:47
Data point term sent to Coder	System	04 Feb 2021 17:37:55
Coding entries removed.	Matthew Musikanth (b) (4)	04 Feb 2021 17:37:40
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: OTHER ANTIBACTERIALS, PRODUCT: BACITRACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 10:30:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 10:30:43
Data point term sent to Coder	System	03 Feb 2021 18:25:12
User entered 'Bacitracin'	Matthew Musikanth (b) (4)	03 Feb 2021 18:24:44

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:24
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Brenda Grande (b) (4)	05 Mar 2021 17:36:26
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:24:44

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:24
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User closed query 'Per DM CLR: Please update the indication and clarify the type of RASH (e.g. maculopapular, pruritic; urticarial vs non-urticarial; etc.) Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 04:35:17
Query 'Per DM CLR: Please update the indication and clarify the type of RASH (e.g. maculopapular, pruritic; urticarial vs non-urticarial; etc.) Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'per pi the indication has been changed ' (Site from DM).	Brenda Grande (b) (4)	05 Mar 2021 17:36:33
User entered 'wound infection prophylaxis' reason for change: Data Entry Error	Brenda Grande (b) (4)	05 Mar 2021 17:36:26
User opened query 'Per DM CLR: Please update the indication and clarify the type of RASH (e.g. maculopapular, pruritic; urticarial vs non-urticarial; etc.) Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 04:46:14
User entered 'Skin Rash L shoulder' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	04 Feb 2021 17:37:40
User entered 'Pinched Nerve'	Matthew Musikanth (b) (4)	03 Feb 2021 18:24:44

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:24
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '50,000'	Matthew Musikanth (b) (4)	03 Feb 2021 18:24:44

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:24
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Other (OTHER)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:24:44

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:24
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'units'	Matthew Musikanth (b) (4)	03 Feb 2021 18:24:44

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:24
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'as needed (PRN)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:24:44

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:11:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:24
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	03 Feb 2021 18:24:44

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:24
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Other (OTHER)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:24:44

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:24
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Injection'	Matthew Musikanth (b) (4)	03 Feb 2021 18:24:44

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:11:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:24
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '26 Oct 2020'	Matthew Musikanth (b) (4)	03 Feb 2021 18:24:44

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:11:47

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:24
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '0'	Matthew Musikanth (b) (4)	03 Feb 2021 18:24:44

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:24
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:24:44

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:24
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '26 Oct 2020'	Matthew Musikanth (b) (4)	03 Feb 2021 18:24:44

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:24
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:24:44

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:24
User entered empty.	System	03 Feb 2021 18:24:44

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:24
User entered empty.	System	03 Feb 2021 18:24:44

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:24
User entered empty.	System	03 Feb 2021 18:24:44

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:11:47

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: OTHER ANTIBACTERIALS, PRODUCT: BACITRACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Mar 2021 04:57:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Mar 2021 04:57:00
Data point term sent to Coder	System	05 Mar 2021 17:37:37
Coding entries removed.	Brenda Grande (b) (4)	05 Mar 2021 17:37:14
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: OTHER ANTIBACTERIALS, PRODUCT: BACITRACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Feb 2021 19:14:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Feb 2021 19:14:47
Data point term sent to Coder	System	04 Feb 2021 17:37:56
Coding entries removed.	Matthew Musikanth (b) (4)	04 Feb 2021 17:37:55
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: OTHER ANTIBACTERIALS, PRODUCT: BACITRACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 10:30:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 10:30:44
Data point term sent to Coder	System	03 Feb 2021 18:27:13
User entered 'Bacitracin'	Matthew Musikanth (b) (4)	03 Feb 2021 18:26:28

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Yes (Y)' reason for change: New Information	Brenda Grande (b) (4)	05 Mar 2021 17:37:14
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:26:28

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User closed query 'Per DM CLR: Please update the indication and clarify the type of RASH (e.g. maculopapular, pruritic; urticarial vs non-urticarial; etc) Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 04:35:24
User entered 'wound infection prophylaxis' reason for change: New Information	Brenda Grande (b) (4)	05 Mar 2021 17:37:14
Query 'Per DM CLR: Please update the indication and clarify the type of RASH (e.g. maculopapular, pruritic; urticarial vs non-urticarial; etc) Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'per pi the indication has been changed ' (Site from DM).	Brenda Grande (b) (4)	05 Mar 2021 17:36:50
User opened query 'Per DM CLR: Please update the indication and clarify the type of RASH (e.g. maculopapular, pruritic; urticarial vs non-urticarial; etc) Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 04:47:10
User entered 'Skin Rash L Shoulder' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	04 Feb 2021 17:37:55
User entered 'Pinched Nerve'	Matthew Musikanth (b) (4)	03 Feb 2021 18:26:28

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '50,000'	Matthew Musikanth (b) (4)	03 Feb 2021 18:26:28

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Other (OTHER)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:26:28

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'units'	Matthew Musikanth (b) (4)	03 Feb 2021 18:26:28

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'as needed (PRN)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:26:28

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:11:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	03 Feb 2021 18:26:28

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Other (OTHER)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:26:28

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Injection'	Matthew Musikanth (b) (4)	03 Feb 2021 18:26:28

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:11:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '28 Oct 2020'	Matthew Musikanth (b) (4)	03 Feb 2021 18:26:28

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '0'	Matthew Musikanth (b) (4)	03 Feb 2021 18:26:28

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:26:28

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '28 Oct 2020'	Matthew Musikanth (b) (4)	03 Feb 2021 18:26:28

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:26:28

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:29
User entered empty.	System	03 Feb 2021 18:26:28

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:29
User entered empty.	System	03 Feb 2021 18:26:28

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:29
User entered empty.	System	03 Feb 2021 18:26:28

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:11:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:51:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: BUPIVACAINE;EPINEPHRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 12:07:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 12:07:44
Data point term sent to Coder	System	03 Feb 2021 18:32:22
User entered 'Bupivacaine - epinephrine .25%'	Matthew Musikanth (b) (4)	03 Feb 2021 18:32:01

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:51:57
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:32:01

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:51:57
User entered 'Pinched Nerve'	Matthew Musikanth (b) (4)	03 Feb 2021 18:32:01

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:51:57
User entered '35'	Matthew Musikanth (b) (4)	03 Feb 2021 18:32:01

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:51:57
User entered 'mL (mL)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:32:01

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:51:57
User entered empty.	Matthew Musikanth (b) (4)	03 Feb 2021 18:32:01

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:51:57
User entered 'as needed (PRN)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:32:01

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:11:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:51:57
User entered empty.	Matthew Musikanth (b) (4)	03 Feb 2021 18:32:01

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:51:57
User entered 'Other (OTHER)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:32:01

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:51:57
User entered 'Injection'	Matthew Musikanth (b) (4)	03 Feb 2021 18:32:01

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:11:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:51:57
User entered '26 Oct 2020'	Matthew Musikanth (b) (4)	03 Feb 2021 18:32:01

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:51:57
User entered '0'	Matthew Musikanth (b) (4)	03 Feb 2021 18:32:01

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:51:57
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:32:01

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:51:57
User entered '26 Oct 2020'	Matthew Musikanth (b) (4)	03 Feb 2021 18:32:01

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:11
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:51:57
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:32:01

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:11
User entered empty.	System	03 Feb 2021 18:32:01

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:11
User entered empty.	System	03 Feb 2021 18:32:01

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:11
User entered empty.	System	03 Feb 2021 18:32:01

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:11:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:40
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTISEPTICS AND DISINFECTANTS, ATC: ANTISEPTICS AND DISINFECTANTS, ATC: IODINE PRODUCTS, PRODUCT: POVIDONE-IODINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 11:51:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 11:51:38
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:52:32
Data point term sent to Coder	System	03 Feb 2021 18:34:23
User entered 'Povidone-iodine 10%'	Matthew Musikanth (b) (4)	03 Feb 2021 18:34:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:40
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:52:32
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:34:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:40
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:52:32
User entered 'Pinched Nerve'	Matthew Musikanth (b) (4)	03 Feb 2021 18:34:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:40
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:52:32
User entered 'I'	Matthew Musikanth (b) (4)	03 Feb 2021 18:34:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:40
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:52:32
User entered 'Other (OTHER)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:34:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:40
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:52:32
User entered 'application'	Matthew Musikanth (b) (4)	03 Feb 2021 18:34:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:40
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:52:32
User entered 'as needed (PRN)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:34:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:11:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:40
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:52:32
User entered empty.	Matthew Musikanth (b) (4)	03 Feb 2021 18:34:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:40
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:52:32
User entered 'Topical (TOPICAL)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:34:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:40
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:52:32
User entered empty.	Matthew Musikanth (b) (4)	03 Feb 2021 18:34:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:11:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:40
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:52:32
User entered '26 Oct 2020'	Matthew Musikanth (b) (4)	03 Feb 2021 18:34:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:40
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:52:32
User entered '0'	Matthew Musikanth (b) (4)	03 Feb 2021 18:34:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:40
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:52:32
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:34:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:40
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:52:32
User entered '26 Oct 2020'	Matthew Musikanth (b) (4)	03 Feb 2021 18:34:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:40
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:52:32
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:34:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:40
User entered empty.	System	03 Feb 2021 18:34:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:40
User entered empty.	System	03 Feb 2021 18:34:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:40
User entered empty.	System	03 Feb 2021 18:34:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:11:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:45
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:54:16
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Feb 2021 11:47:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Feb 2021 11:47:45
Data point term sent to Coder	System	03 Feb 2021 18:36:24
User entered 'Vancomycin'	Matthew Musikanth (b) (4)	03 Feb 2021 18:36:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:45
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:54:16
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:36:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:45
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:54:16
User entered 'Pinched Nerve'	Matthew Musikanth (b) (4)	03 Feb 2021 18:36:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:45
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:54:16
User entered 'I'	Matthew Musikanth (b) (4)	03 Feb 2021 18:36:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:45
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:54:16
User entered 'g (g)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:36:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:45
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:54:16
User entered empty.	Matthew Musikanth (b) (4)	03 Feb 2021 18:36:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:45
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:54:16
User entered 'as needed (PRN)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:36:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:11:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:45
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:54:16
User entered empty.	Matthew Musikanth (b) (4)	03 Feb 2021 18:36:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:45
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:54:16
User entered 'Other (OTHER)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:36:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:45
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:54:16
User entered 'Injection'	Matthew Musikanth (b) (4)	03 Feb 2021 18:36:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:11:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:45
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:54:16
User entered '26 Oct 2020'	Matthew Musikanth (b) (4)	03 Feb 2021 18:36:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:45
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:54:16
User entered '0'	Matthew Musikanth (b) (4)	03 Feb 2021 18:36:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:45
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:54:16
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:36:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:45
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:54:16
User entered '26 Oct 2020'	Matthew Musikanth (b) (4)	03 Feb 2021 18:36:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:45
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:54:16
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:36:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:45
User entered empty.	System	03 Feb 2021 18:36:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:45
User entered empty.	System	03 Feb 2021 18:36:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:45
User entered empty.	System	03 Feb 2021 18:36:12

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:11:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:54:57
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 11:47:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 11:47:45
Data point term sent to Coder	System	03 Feb 2021 18:39:27
User entered 'Vancomycin'	Matthew Musikanth (b) (4)	03 Feb 2021 18:39:24

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:54:57
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:39:24

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:54:57
User entered 'Pinched Nerve'	Matthew Musikanth (b) (4)	03 Feb 2021 18:39:24

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:54:57
User entered 'I'	Matthew Musikanth (b) (4)	03 Feb 2021 18:39:24

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:54:57
User entered 'g (g)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:39:24

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:54:57
User entered empty.	Matthew Musikanth (b) (4)	03 Feb 2021 18:39:24

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:54:57
User entered 'as needed (PRN)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:39:24

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:11:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:54:57
User entered empty.	Matthew Musikanth (b) (4)	03 Feb 2021 18:39:24

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:54:57
User entered 'Other (OTHER)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:39:24

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:54:57
User entered 'Injection'	Matthew Musikanth (b) (4)	03 Feb 2021 18:39:24

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:11:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:54:57
User entered '28 Oct 2020'	Matthew Musikanth (b) (4)	03 Feb 2021 18:39:24

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:54:57
User entered '0'	Matthew Musikanth (b) (4)	03 Feb 2021 18:39:24

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:54:57
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:39:24

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:54:57
User entered '28 Oct 2020'	Matthew Musikanth (b) (4)	03 Feb 2021 18:39:24

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:49
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:54:57
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:39:24

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:49
User entered empty.	System	03 Feb 2021 18:39:24

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:49
User entered empty.	System	03 Feb 2021 18:39:24

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:49
User entered empty.	System	03 Feb 2021 18:39:24

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:11:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:55:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 10:43:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 10:43:45
Data point term sent to Coder	System	03 Feb 2021 18:40:27
User entered 'Fentanyl'	Matthew Musikanth (b) (4)	03 Feb 2021 18:40:23

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:55:36
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:40:23

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:55:36
User entered 'Pinched Nerve'	Matthew Musikanth (b) (4)	03 Feb 2021 18:40:23

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:55:36
User entered '50'	Matthew Musikanth (b) (4)	03 Feb 2021 18:40:23

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:55:36
User entered 'Other (OTHER)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:40:23

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:55:36
User entered 'mcg'	Matthew Musikanth (b) (4)	03 Feb 2021 18:40:23

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:55:36
User entered 'as needed (PRN)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:40:23

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:11:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:55:36
User entered empty.	Matthew Musikanth (b) (4)	03 Feb 2021 18:40:23

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:55:36
User entered 'Other (OTHER)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:40:23

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:55:36
User entered 'Injection'	Matthew Musikanth (b) (4)	03 Feb 2021 18:40:23

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:11:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:55:36
User entered '26 Oct 2020'	Matthew Musikanth (b) (4)	03 Feb 2021 18:40:23

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:55:36
User entered '0'	Matthew Musikanth (b) (4)	03 Feb 2021 18:40:23

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:55:36
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:40:23

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:55:36
User entered '26 Oct 2020'	Matthew Musikanth (b) (4)	03 Feb 2021 18:40:23

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:55:36
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:40:23

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:58
User entered empty.	System	03 Feb 2021 18:40:23

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:58
User entered empty.	System	03 Feb 2021 18:40:23

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:10:58
User entered empty.	System	03 Feb 2021 18:40:23

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:11:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:19
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:56:43
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 10:58:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 10:58:49
Data point term sent to Coder	System	03 Feb 2021 18:42:40
User entered 'Fentanyl'	Matthew Musikanth (b) (4)	03 Feb 2021 18:41:48

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:19
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:56:43
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:41:48

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:19
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:56:43
User entered 'Pinched Nerve'	Matthew Musikanth (b) (4)	03 Feb 2021 18:41:48

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:19
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:56:43
User entered '50'	Matthew Musikanth (b) (4)	03 Feb 2021 18:41:48

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:19
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:56:43
User entered 'Other (OTHER)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:41:48

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:19
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:56:43
User entered 'mcg'	Matthew Musikanth (b) (4)	03 Feb 2021 18:41:48

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:19
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:56:43
User entered 'as needed (PRN)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:41:48

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:11:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:19
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:56:43
User entered empty.	Matthew Musikanth (b) (4)	03 Feb 2021 18:41:48

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:19
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:56:43
User entered 'Other (OTHER)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:41:48

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:19
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:56:43
User entered 'Injection'	Matthew Musikanth (b) (4)	03 Feb 2021 18:41:48

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:11:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:19
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:56:43
User entered '28 Oct 2020'	Matthew Musikanth (b) (4)	03 Feb 2021 18:41:48

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:19
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:56:43
User entered '0'	Matthew Musikanth (b) (4)	03 Feb 2021 18:41:48

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:19
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:56:43
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:41:48

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:19
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:56:43
User entered '28 Oct 2020'	Matthew Musikanth (b) (4)	03 Feb 2021 18:41:48

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:19
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:56:43
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:41:48

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:19
User entered empty.	System	03 Feb 2021 18:41:48

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:19
User entered empty.	System	03 Feb 2021 18:41:48

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:19
User entered empty.	System	03 Feb 2021 18:41:48

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:11:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:24
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:58:17
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 11:48:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 11:48:44
Data point term sent to Coder	System	03 Feb 2021 18:43:41
User entered 'Zofran'	Matthew Musikanth (b) (4)	03 Feb 2021 18:42:45

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:24
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:58:17
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:42:45

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:24
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:58:17
User entered 'Pinched Nerve'	Matthew Musikanth (b) (4)	03 Feb 2021 18:42:45

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:24
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:58:17
User entered '4'	Matthew Musikanth (b) (4)	03 Feb 2021 18:42:45

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:24
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:58:17
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:42:45

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:24
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:58:17
User entered empty.	Matthew Musikanth (b) (4)	03 Feb 2021 18:42:45

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:24
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:58:17
User entered 'as needed (PRN)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:42:45

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:11:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:24
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:58:17
User entered empty.	Matthew Musikanth (b) (4)	03 Feb 2021 18:42:45

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:24
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:58:17
User entered 'Other (OTHER)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:42:45

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:24
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:58:17
User entered 'Injection'	Matthew Musikanth (b) (4)	03 Feb 2021 18:42:45

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:11:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:24
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:58:17
User entered '26 Oct 2020'	Matthew Musikanth (b) (4)	03 Feb 2021 18:42:45

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:24
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:58:17
User entered '0'	Matthew Musikanth (b) (4)	03 Feb 2021 18:42:45

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:24
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:58:17
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:42:45

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:24
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 23:49:14
User closed query 'Please clarify. Source indicates stop date of 30Oct2020. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 23:49:10
Query 'Please clarify. Source indicates stop date of 30Oct2020. Please confirm and update as necessary.' answered with 'Updated' (Site from CRA).	Matthew Musikanth (b) (4)	17 Feb 2021 23:11:47
DataPoint Un-verified.	Matthew Musikanth (b) (4)	17 Feb 2021 23:11:43
User entered '30 Oct 2020' reason for change: Data Entry Error	Matthew Musikanth (b) (4)	17 Feb 2021 23:11:43
User opened query 'Please clarify. Source indicates stop date of 30Oct2020. Please confirm and update as necessary.' (Site from CRA).	(b) (4), (b) (6)	17 Feb 2021 22:58:45
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:58:17
User entered '26 Oct 2020'	Matthew Musikanth (b) (4)	03 Feb 2021 18:42:45

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:24
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:58:17
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:42:45

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:24
User entered empty.	System	03 Feb 2021 18:42:45

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:24
User entered empty.	System	03 Feb 2021 18:42:45

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:24
User entered empty.	System	03 Feb 2021 18:42:45

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:11:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:59:18
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL, PRODUCTSYNONYM: ROBAXIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Feb 2021 18:47:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Feb 2021 18:47:27
Data point term sent to Coder	System	03 Feb 2021 18:46:43
User entered 'Robaxin'	Matthew Musikanth (b) (4)	03 Feb 2021 18:46:14

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:59:18
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:46:14

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:59:18
User entered 'Pinched Nerve'	Matthew Musikanth (b) (4)	03 Feb 2021 18:46:14

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:59:18
User entered '750'	Matthew Musikanth (b) (4)	03 Feb 2021 18:46:14

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:59:18
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:46:14

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:59:18
User entered empty.	Matthew Musikanth (b) (4)	03 Feb 2021 18:46:14

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:59:18
User entered 'other (OTHER)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:46:14

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:11:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:59:18
User entered 'q8hrs'	Matthew Musikanth (b) (4)	03 Feb 2021 18:46:14

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:59:18
User entered 'Intravenous (INTRAVENOUS)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:46:14

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:59:18
User entered empty.	Matthew Musikanth (b) (4)	03 Feb 2021 18:46:14

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:11:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:59:18
User entered '26 Oct 2020'	Matthew Musikanth (b) (4)	03 Feb 2021 18:46:14

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:59:18
User entered '0'	Matthew Musikanth (b) (4)	03 Feb 2021 18:46:14

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:59:18
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:46:14

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:59:18
User entered '28 Oct 2020'	Matthew Musikanth (b) (4)	03 Feb 2021 18:46:14

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:59:18
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:46:14

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:29
User entered empty.	System	03 Feb 2021 18:46:14

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:29
User entered empty.	System	03 Feb 2021 18:46:14

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:29
User entered empty.	System	03 Feb 2021 18:46:14

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:11:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:34
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:00:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE HYDROCHLORIDE, PRODUCTSYNONYM: OXYCONTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Feb 2021 18:50:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Feb 2021 18:50:27
Data point term sent to Coder	System	03 Feb 2021 18:49:46
User entered 'Oxycontin'	Matthew Musikanth (b) (4)	03 Feb 2021 18:49:45

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:34
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:00:34
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:49:45

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:34
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:00:34
User entered 'Pinched Nerve'	Matthew Musikanth (b) (4)	03 Feb 2021 18:49:45

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:34
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:00:34
User entered '10'	Matthew Musikanth (b) (4)	03 Feb 2021 18:49:45

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:34
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:00:34
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:49:45

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:34
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:00:34
User entered empty.	Matthew Musikanth (b) (4)	03 Feb 2021 18:49:45

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:34
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:00:34
User entered 'other (OTHER)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:49:45

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:11:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:34
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:00:34
User entered 'q12hrs'	Matthew Musikanth (b) (4)	03 Feb 2021 18:49:45

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:34
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:00:34
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:49:45

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:34
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:00:34
User entered empty.	Matthew Musikanth (b) (4)	03 Feb 2021 18:49:45

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:11:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:34
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:00:34
User entered '26 Oct 2020'	Matthew Musikanth (b) (4)	03 Feb 2021 18:49:45

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:34
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:00:34
User entered '0'	Matthew Musikanth (b) (4)	03 Feb 2021 18:49:45

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:34
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:00:34
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:49:45

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:34
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:00:34
User entered '28 Oct 2020'	Matthew Musikanth (b) (4)	03 Feb 2021 18:49:45

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:34
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:00:34
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:49:45

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:34
User entered empty.	System	03 Feb 2021 18:49:45

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:34
User entered empty.	System	03 Feb 2021 18:49:45

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:34
User entered empty.	System	03 Feb 2021 18:49:45

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:11:47

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:42
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:01:59
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: PERCOCET [OXYCODONE HYDROCHLORIDE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 11:28:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 11:28:46
Data point term sent to Coder	System	03 Feb 2021 18:50:47
User entered 'Percocet'	Matthew Musikanth (b) (4)	03 Feb 2021 18:50:43

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:42
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:01:59
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:50:43

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:42
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:01:59
User entered 'Pinched Nerve'	Matthew Musikanth (b) (4)	03 Feb 2021 18:50:43

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:42
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:01:59
User entered '5-325'	Matthew Musikanth (b) (4)	03 Feb 2021 18:50:43

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:42
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:01:59
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:50:43

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:42
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:01:59
User entered empty.	Matthew Musikanth (b) (4)	03 Feb 2021 18:50:43

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:42
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:23:19
DataPoint Un-verified.	Matthew Musikanth	17 Feb 2021 23:12:20
User entered 'other (OTHER)' reason for change:	(b) (4)	
Data Entry Error	Matthew Musikanth	17 Feb 2021 23:12:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Feb 2021 23:01:59
User entered 'as needed (PRN)'	Matthew Musikanth	03 Feb 2021 18:50:43
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:11:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:42
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:23:21
DataPoint Un-verified.	Matthew Musikanth	17 Feb 2021 23:12:20
User entered 'prn q4hrs' reason for change: Data Entry Error	Matthew Musikanth	17 Feb 2021 23:12:20
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:01:59
User entered empty.	Matthew Musikanth	03 Feb 2021 18:50:43

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:42
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:01:59
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:50:43

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:42
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:01:59
User entered empty.	Matthew Musikanth (b) (4)	03 Feb 2021 18:50:43

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:11:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:42
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:01:59
User entered '27 Oct 2020'	Matthew Musikanth (b) (4)	03 Feb 2021 18:50:43

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:42
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:01:59
User entered '0'	Matthew Musikanth (b) (4)	03 Feb 2021 18:50:43

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:42
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:01:59
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:50:43

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:42
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:01:59
User entered '27 Oct 2020'	Matthew Musikanth (b) (4)	03 Feb 2021 18:50:43

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:42
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:01:59
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 18:50:43

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:42
User entered empty.	System	03 Feb 2021 18:50:43

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:42
User entered empty.	System	03 Feb 2021 18:50:43

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:42
User entered empty.	System	03 Feb 2021 18:50:43

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:11:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:48
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:02:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE HYDROCHLORIDE, PRODUCTSYNONYM: DILAUDID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Feb 2021 19:12:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Feb 2021 19:12:27
Data point term sent to Coder	System	03 Feb 2021 19:12:08
User entered 'Dilaudid'	Matthew Musikanth (b) (4)	03 Feb 2021 19:11:46

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:48
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:02:47
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 19:11:46

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:48
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:02:47
User entered 'Pinched Nerve'	Matthew Musikanth (b) (4)	03 Feb 2021 19:11:46

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:48
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:02:47
User entered 'I'	Matthew Musikanth (b) (4)	03 Feb 2021 19:11:46

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:48
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:02:47
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	03 Feb 2021 19:11:46

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:48
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:02:47
User entered empty.	Matthew Musikanth (b) (4)	03 Feb 2021 19:11:46

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:48
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:02:47
User entered 'other (OTHER)'	Matthew Musikanth (b) (4)	03 Feb 2021 19:11:46

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:11:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:48
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:02:47
User entered 'q3hr prn'	Matthew Musikanth (b) (4)	03 Feb 2021 19:11:46

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:48
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:02:47
User entered 'Other (OTHER)'	Matthew Musikanth (b) (4)	03 Feb 2021 19:11:46

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:48
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:02:47
User entered 'Injection'	Matthew Musikanth (b) (4)	03 Feb 2021 19:11:46

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:11:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:48
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:02:47
User entered '26 Oct 2020'	Matthew Musikanth (b) (4)	03 Feb 2021 19:11:46

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:48
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:02:47
User entered '0'	Matthew Musikanth (b) (4)	03 Feb 2021 19:11:46

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:48
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:02:47
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 19:11:46

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:48
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:02:47
User entered '30 Oct 2020'	Matthew Musikanth (b) (4)	03 Feb 2021 19:11:46

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:48
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:02:47
User entered 'No (N)'	Matthew Musikanth (b) (4)	03 Feb 2021 19:11:46

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:48
User entered empty.	System	03 Feb 2021 19:11:46

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:48
User entered empty.	System	03 Feb 2021 19:11:46

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:48
User entered empty.	System	03 Feb 2021 19:11:46

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:11:47

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:55
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE, PRODUCTSYNONYM: CLARITIN [LORATADINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 20:54:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 20:54:27
Data point term sent to Coder	System	04 Feb 2021 17:39:58
User entered 'Claritin'	Matthew Musikanth (b) (4)	04 Feb 2021 17:39:19

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:55
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:39:19

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:55
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Hayfever'	Matthew Musikanth (b) (4)	04 Feb 2021 17:39:19

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:55
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'I'	Matthew Musikanth (b) (4)	04 Feb 2021 17:39:19

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:55
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:39:19

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:55
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	04 Feb 2021 17:39:19

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:55
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'other (OTHER)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:39:19

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:11:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:55
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'q3hr prn'	Matthew Musikanth (b) (4)	04 Feb 2021 17:39:19

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:55
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Intravenous (INTRAVENOUS)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:39:19

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:55
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	04 Feb 2021 17:39:19

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:11:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:55
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '26 Oct 2020'	Matthew Musikanth (b) (4)	04 Feb 2021 17:39:19

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:55
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '0'	Matthew Musikanth (b) (4)	04 Feb 2021 17:39:19

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:55
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:39:19

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:55
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '30 Oct 2020'	Matthew Musikanth (b) (4)	04 Feb 2021 17:39:19

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:55
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:39:19

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:55
User entered empty.	System	04 Feb 2021 17:39:19

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:55
User entered empty.	System	04 Feb 2021 17:39:19

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:11:55
User entered empty.	System	04 Feb 2021 17:39:19

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:11:47

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE, PRODUCTSYNONYM: CLARITIN [LORATADINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 17:41:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 17:41:47
Data point term sent to Coder	System	04 Feb 2021 17:40:59
User entered 'Claritin'	Matthew Musikanth (b) (4)	04 Feb 2021 17:40:10

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:40:10

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Hayfever'	Matthew Musikanth (b) (4)	04 Feb 2021 17:40:10

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '10'	Matthew Musikanth (b) (4)	04 Feb 2021 17:40:10

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:40:10

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	04 Feb 2021 17:40:10

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'once daily (QD)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:40:10

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:11:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	04 Feb 2021 17:40:10

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:40:10

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	04 Feb 2021 17:40:10

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:11:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '26 Oct 2020'	Matthew Musikanth (b) (4)	04 Feb 2021 17:40:10

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '0'	Matthew Musikanth (b) (4)	04 Feb 2021 17:40:10

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:40:10

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '30 Oct 2020'	Matthew Musikanth (b) (4)	04 Feb 2021 17:40:10

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:18
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:40:10

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:18
User entered '1'	System	04 Feb 2021 17:40:10

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:18
User entered '1'	System	04 Feb 2021 17:40:10

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:18
User entered '804 (804)'	System	04 Feb 2021 17:40:10

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:11:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM, PRODUCTSYNONYM: COLACE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 17:41:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 17:41:48
Data point term sent to Coder	System	04 Feb 2021 17:41:00
User entered 'Colace'	Matthew Musikanth (b) (4)	04 Feb 2021 17:40:47

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth	04 Feb 2021 17:40:47
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Constipation'	Matthew Musikanth (b) (4)	04 Feb 2021 17:40:47

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '200'	Matthew Musikanth (b) (4)	04 Feb 2021 17:40:47

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:40:47

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	04 Feb 2021 17:40:47
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'as needed (PRN)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:40:47

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:11:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	04 Feb 2021 17:40:47
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:40:47

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	04 Feb 2021 17:40:47
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:11:47

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'un UNK 2019'	Matthew Musikanth (b) (4)	04 Feb 2021 17:40:47

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '0'	Matthew Musikanth (b) (4)	04 Feb 2021 17:40:47

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:40:47

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	04 Feb 2021 17:40:47
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:40:47

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Feb 2021 17:40:47

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Feb 2021 17:40:47

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Feb 2021 17:40:47

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:11:47

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:22
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening CONSTIPATION should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 04:35:39
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening CONSTIPATION should be recorded, and update con med indication or provide clarification. ' answered with 'no worsening of constipation' (Site from DM).	Brenda Grande (b) (4)	05 Mar 2021 17:38:20
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening CONSTIPATION should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 04:54:40
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL 3350, PRODUCTS YNOM: GLYCOLAX - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Feb 2021 17:44:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Feb 2021 17:44:01
Data point term sent to Coder	System	04 Feb 2021 17:42:01
User entered 'Glycolax'	Matthew Musikanth (b) (4)	04 Feb 2021 17:41:26

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:22
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:41:26

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:22
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Constipation'	Matthew Musikanth (b) (4)	04 Feb 2021 17:41:26

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:22
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '17'	Matthew Musikanth (b) (4)	04 Feb 2021 17:41:26

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:22
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:41:26

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:22
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	04 Feb 2021 17:41:26

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:22
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'twice daily (BID)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:41:26

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:11:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:22
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	04 Feb 2021 17:41:26

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:22
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:41:26

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:22
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	04 Feb 2021 17:41:26

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:11:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:22
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '26 Oct 2020'	Matthew Musikanth (b) (4)	04 Feb 2021 17:41:26

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:22
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '0'	Matthew Musikanth (b) (4)	04 Feb 2021 17:41:26

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:22
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:41:26

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:22
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '30 Oct 2020'	Matthew Musikanth (b) (4)	04 Feb 2021 17:41:26

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:22
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:41:26

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:22
User entered '2'	System	04 Feb 2021 17:41:26

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:22
User entered '1'	System	04 Feb 2021 17:41:26

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:22
User entered '804 (804)'	System	04 Feb 2021 17:41:26

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:11:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:15
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: SENNOSIDE A+B, PRODUCTSYNONYM: SENOKOT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 17:44:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 17:44:03
Data point term sent to Coder	System	04 Feb 2021 17:43:02
User entered 'Senokot'	Matthew Musikanth (b) (4)	04 Feb 2021 17:42:13

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:15
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:42:13

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:15
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Constipation'	Matthew Musikanth (b) (4)	04 Feb 2021 17:42:13

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:15
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '17.2'	Matthew Musikanth (b) (4)	04 Feb 2021 17:42:13

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:15
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:42:13

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:15
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	04 Feb 2021 17:42:13

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:15
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'other (OTHER)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:42:13

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:11:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:15
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'qhs'	Matthew Musikanth (b) (4)	04 Feb 2021 17:42:13

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:15
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:42:13

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:15
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	04 Feb 2021 17:42:13

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:11:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:15
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '26 Oct 2020'	Matthew Musikanth (b) (4)	04 Feb 2021 17:42:13

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:15
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '0'	Matthew Musikanth (b) (4)	04 Feb 2021 17:42:13

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:15
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:42:13

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:15
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '30 Oct 2020'	Matthew Musikanth (b) (4)	04 Feb 2021 17:42:13

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:15
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:42:13

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:15
User entered empty.	System	04 Feb 2021 17:42:13

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:15
User entered empty.	System	04 Feb 2021 17:42:13

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:15
User entered empty.	System	04 Feb 2021 17:42:13

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:11:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS, PRODUCT: GLUCOSAMINE SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 22:42:30
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 22:42:30
	(b) (4)	
Data point term sent to Coder	System	04 Feb 2021 17:45:07
User entered 'Glucosamine-sulfate'	Matthew Musikanth	04 Feb 2021 17:44:28
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 04:35:55
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'updated ' (Site from DM).	Brenda Grande (b) (4)	05 Mar 2021 17:39:21
User entered 'Yes (Y)' reason for change: Data Entry Error	Brenda Grande (b) (4)	05 Mar 2021 17:39:06
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 04:55:20
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:44:28

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'supplement'	Matthew Musikanth	04 Feb 2021 17:44:28
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '500'	Matthew Musikanth	04 Feb 2021 17:44:28
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:44:28

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	04 Feb 2021 17:44:28
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'twice daily (BID)'	Matthew Musikanth	04 Feb 2021 17:44:28
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:11:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	04 Feb 2021 17:44:28
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:44:28

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	04 Feb 2021 17:44:28
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:11:47

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '15 Mar 2010'	Matthew Musikanth (b) (4)	04 Feb 2021 17:44:28

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:11:47

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '0'	Matthew Musikanth (b) (4)	04 Feb 2021 17:44:28

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:44:28

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	04 Feb 2021 17:44:28
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:44:28

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	04 Feb 2021 17:44:28

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Feb 2021 17:44:28

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Feb 2021 17:44:28

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:11:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:04:43
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE, PRODUCTSYNONYM: DECADRON [DEXAMETHASONE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Feb 2021 20:55:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Feb 2021 20:55:27
Data point term sent to Coder	System	04 Feb 2021 17:46:08
User entered 'Decadron'	Matthew Musikanth (b) (4)	04 Feb 2021 17:45:37

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:04:43
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:45:37

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:04:43
User entered 'Pinched Nerve'	Matthew Musikanth (b) (4)	04 Feb 2021 17:45:37

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:04:43
User entered '8'	Matthew Musikanth (b) (4)	04 Feb 2021 17:45:37

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:04:43
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:45:37

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:04:43
User entered empty.	Matthew Musikanth (b) (4)	04 Feb 2021 17:45:37

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:04:43
User entered 'other (OTHER)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:45:37

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:11:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:04:43
User entered 'q6hr'	Matthew Musikanth (b) (4)	04 Feb 2021 17:45:37

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:04:43
User entered 'Other (OTHER)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:45:37

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:04:43
User entered 'Injection'	Matthew Musikanth (b) (4)	04 Feb 2021 17:45:37

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:11:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:04:43
User entered '27 Oct 2020'	Matthew Musikanth (b) (4)	04 Feb 2021 17:45:37

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:04:43
User entered '0'	Matthew Musikanth (b) (4)	04 Feb 2021 17:45:37

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:04:43
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:45:37

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:04:43
User entered '29 Oct 2020'	Matthew Musikanth (b) (4)	04 Feb 2021 17:45:37

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:04:43
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:45:37

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:47
User entered empty.	System	04 Feb 2021 17:45:37

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:47
User entered empty.	System	04 Feb 2021 17:45:37

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:47
User entered empty.	System	04 Feb 2021 17:45:37

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:11:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:31
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening GERD should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 04:36:05
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening GERD should be recorded, and update con med indication or provide clarification. ' answered with 'no worsening of GERD' (Site from DM).	Brenda Grande (b) (4)	05 Mar 2021 17:40:12
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening GERD should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 04:57:38
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE, PRODUCTSYNONYM: PEPCID [FAMOTIDINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 17:47:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 17:47:47
Data point term sent to Coder	System	04 Feb 2021 17:47:09
User entered 'Pepcid'	Matthew Musikanth (b) (4)	04 Feb 2021 17:46:19

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:31
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:46:19

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:31
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'GERD'	Matthew Musikanth (b) (4)	04 Feb 2021 17:46:19

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:31
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '20'	Matthew Musikanth (b) (4)	04 Feb 2021 17:46:19

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:31
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:46:19

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:31
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	04 Feb 2021 17:46:19

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:31
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'twice daily (BID)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:46:19

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:11:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:31
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	04 Feb 2021 17:46:19

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:31
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:46:19

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:31
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	04 Feb 2021 17:46:19

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:11:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:31
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '28 Oct 2020'	Matthew Musikanth (b) (4)	04 Feb 2021 17:46:19

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:31
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '0'	Matthew Musikanth (b) (4)	04 Feb 2021 17:46:19

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:31
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:46:19

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:31
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '30 Oct 2020'	Matthew Musikanth (b) (4)	04 Feb 2021 17:46:19

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:31
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:46:19

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:31
User entered '2'	System	04 Feb 2021 17:46:19

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:31
User entered '1'	System	04 Feb 2021 17:46:19

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:31
User entered '804 (804)'	System	04 Feb 2021 17:46:19

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:11:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STERIODS, PRODUCT: CHONDROITIN;GLUCOSAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 17:48:47
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	04 Feb 2021 17:48:47
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	04 Feb 2021 17:48:10
User entered 'Glucosamine-chondroitin'	Matthew Musikanth	04 Feb 2021 17:48:05
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 04:36:21
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'updated' (Site from DM).	Brenda Grande (b) (4)	05 Mar 2021 17:40:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Brenda Grande (b) (4)	05 Mar 2021 17:40:39
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 04:57:57
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:48:05

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Supplement'	Matthew Musikanth (b) (4)	04 Feb 2021 17:48:05

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '500/400'	Matthew Musikanth (b) (4)	04 Feb 2021 17:48:05

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:48:05

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	04 Feb 2021 17:48:05
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'twice daily (BID)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:48:05

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:11:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	04 Feb 2021 17:48:05

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:48:05

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	04 Feb 2021 17:48:05
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:11:47

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '15 Mar 2010'	Matthew Musikanth (b) (4)	04 Feb 2021 17:48:05

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '0'	Matthew Musikanth (b) (4)	04 Feb 2021 17:48:05

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:48:05

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	04 Feb 2021 17:48:05
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:48:05

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	04 Feb 2021 17:48:05

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Feb 2021 17:48:05

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Feb 2021 17:48:05

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:11:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 17:52:08
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 17:52:08
	(b) (4)	
Data point term sent to Coder	System	04 Feb 2021 17:51:15
User entered 'Hydrochlorothiazide'	Matthew Musikanth	04 Feb 2021 17:50:30
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth	04 Feb 2021 17:50:30
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Hypertension'	Matthew Musikanth	04 Feb 2021 17:50:30
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '12.5'	Matthew Musikanth (b) (4)	04 Feb 2021 17:50:30

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:50:30

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	04 Feb 2021 17:50:30

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'once daily (QD)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:50:30

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:11:47

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	04 Feb 2021 17:50:30
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:50:30

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	04 Feb 2021 17:50:30
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:11:47

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'un UNK 2016'	Matthew Musikanth (b) (4)	04 Feb 2021 17:50:30

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:11:47

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '0'	Matthew Musikanth	04 Feb 2021 17:50:30
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:50:30

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	04 Feb 2021 17:50:30
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:50:30

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Feb 2021 17:50:30

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Feb 2021 17:50:30

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Feb 2021 17:50:30

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:11:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 17:53:52
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	04 Feb 2021 17:53:52
User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	04 Feb 2021 17:53:20
User entered 'Lisinopril'	Matthew Musikanth (b) (4)	04 Feb 2021 17:53:07

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:53:07

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Hypertension'	Matthew Musikanth (b) (4)	04 Feb 2021 17:53:07

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '20'	Matthew Musikanth (b) (4)	04 Feb 2021 17:53:07

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:53:07

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	04 Feb 2021 17:53:07

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'once daily (QD)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:53:07

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:11:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	04 Feb 2021 17:53:07

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:53:07

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	04 Feb 2021 17:53:07

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:11:47

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'un UNK 2016'	Matthew Musikanth (b) (4)	04 Feb 2021 17:53:07

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:11:47

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '0'	Matthew Musikanth (b) (4)	04 Feb 2021 17:53:07

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:53:07

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	04 Feb 2021 17:53:07
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:53:07

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Feb 2021 17:53:07

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Feb 2021 17:53:07

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Feb 2021 17:53:07

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:11:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 18:09:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 18:09:49
Data point term sent to Coder	System	04 Feb 2021 17:54:21
User entered 'Pantoprazole'	Matthew Musikanth (b) (4)	04 Feb 2021 17:53:46

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:53:46

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'GERD'	Matthew Musikanth (b) (4)	04 Feb 2021 17:53:46

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '40'	Matthew Musikanth (b) (4)	04 Feb 2021 17:53:46

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:53:46

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	04 Feb 2021 17:53:46

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'once daily (QD)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:53:46

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:11:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	04 Feb 2021 17:53:46

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:53:46

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	04 Feb 2021 17:53:46

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:11:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '27 Oct 2020'	Matthew Musikanth (b) (4)	04 Feb 2021 17:53:46

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '0'	Matthew Musikanth (b) (4)	04 Feb 2021 17:53:46

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:53:46

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '27 Oct 2020'	Matthew Musikanth (b) (4)	04 Feb 2021 17:53:46

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:58
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:53:46

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:58
User entered '1'	System	04 Feb 2021 17:53:46

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:58
User entered '1'	System	04 Feb 2021 17:53:46

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:58
User entered '804 (804)'	System	04 Feb 2021 17:53:46

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:11:47

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:39
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERLIPIDEMIA should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 04:36:30
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERLIPIDEMIA should be recorded, and update con med indication or provide clarification. ' answered with 'no worsening of hyperlipidemia ' (Site from DM).	Brenda Grande (b) (4)	05 Mar 2021 17:41:28
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERLIPIDEMIA should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 04:59:31
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 17:55:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 17:55:50
Data point term sent to Coder	System	04 Feb 2021 17:55:22
User entered 'Atorvastatin'	Matthew Musikanth (b) (4)	04 Feb 2021 17:54:31

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:39
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:54:31

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:39
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Hyperlipidemia'	Matthew Musikanth (b) (4)	04 Feb 2021 17:54:31

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:39
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '80'	Matthew Musikanth (b) (4)	04 Feb 2021 17:54:31

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:39
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:54:31

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:39
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	04 Feb 2021 17:54:31

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:39
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'once daily (QD)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:54:31

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:11:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:39
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	04 Feb 2021 17:54:31

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:39
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:54:31

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:39
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	04 Feb 2021 17:54:31

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:11:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:39
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '26 Oct 2020'	Matthew Musikanth (b) (4)	04 Feb 2021 17:54:31

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:39
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '0'	Matthew Musikanth (b) (4)	04 Feb 2021 17:54:31

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:39
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:54:31

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:39
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '30 Oct 2020'	Matthew Musikanth (b) (4)	04 Feb 2021 17:54:31

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:39
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:54:31

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:39
User entered '1'	System	04 Feb 2021 17:54:31

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:39
User entered '1'	System	04 Feb 2021 17:54:31

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:39
User entered '804 (804)'	System	04 Feb 2021 17:54:31

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:11:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:46
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS FOR URINARY FREQUENCY AND INCONTINENCE, PRODUCT: OXYBUTYNIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 23:04:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 23:04:35
Data point term sent to Coder	System	04 Feb 2021 17:56:23
User entered 'Oxybutynin'	Matthew Musikanth (b) (4)	04 Feb 2021 17:55:38

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:46
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:55:38

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:46
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'BPH'	Matthew Musikanth (b) (4)	04 Feb 2021 17:55:38

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:46
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '5'	Matthew Musikanth (b) (4)	04 Feb 2021 17:55:38

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:46
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:55:38

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:46
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	04 Feb 2021 17:55:38

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:46
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'three times daily (TID)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:55:38

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:11:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:46
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	04 Feb 2021 17:55:38

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:46
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:55:38

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:46
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	04 Feb 2021 17:55:38

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:11:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:46
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '26 Oct 2020'	Matthew Musikanth (b) (4)	04 Feb 2021 17:55:38

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:46
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '0'	Matthew Musikanth (b) (4)	04 Feb 2021 17:55:38

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:46
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:55:38

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:46
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '30 Oct 2020'	Matthew Musikanth (b) (4)	04 Feb 2021 17:55:38

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:46
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:55:38

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:46
User entered '3'	System	04 Feb 2021 17:55:38

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:46
User entered '1'	System	04 Feb 2021 17:55:38

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:46
User entered '804 (804)'	System	04 Feb 2021 17:55:38

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:11:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, MODERATELY POTENT (GROUP II), PRODUCT: TRIAMCINOLONE ACETONIDE, PRODUCTSYNONYM: KENALOG [TRIAMCINOLONE ACETONIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Feb 2021 13:10:52
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Feb 2021 13:10:52
	(b) (4)	
Data point term sent to Coder	System	04 Feb 2021 17:56:24
User entered 'Kenalog'	Matthew Musikanth	04 Feb 2021 17:56:19
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:56:19

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Skin Rash L Shoulder'	Matthew Musikanth (b) (4)	04 Feb 2021 17:56:19

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '1'	Matthew Musikanth (b) (4)	04 Feb 2021 17:56:19

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Other (OTHER)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:56:19

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'application'	Matthew Musikanth (b) (4)	04 Feb 2021 17:56:19

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'twice daily (BID)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:56:19

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:11:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	04 Feb 2021 17:56:19
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Topical (TOPICAL)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:56:19

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	04 Feb 2021 17:56:19

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:11:47

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '08 Feb 2020'	Matthew Musikanth (b) (4)	04 Feb 2021 17:56:19

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:11:47

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '0'	Matthew Musikanth (b) (4)	04 Feb 2021 17:56:19

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:56:19

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	04 Feb 2021 17:56:19
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:56:19

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	04 Feb 2021 17:56:19

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Feb 2021 17:56:19

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Feb 2021 17:56:19

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:11:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening TYPE 2 DIABETES should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 04:36:59
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening TYPE 2 DIABETES should be recorded, and update con med indication or provide clarification. ' answered with 'per subjects account no worsenign of type 2 diabetes ' (Site from DM).	Brenda Grande (b) (4)	05 Mar 2021 17:49:52
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening TYPE 2 DIABETES should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 05:01:32
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)	04 Feb 2021 17:59:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 17:59:50
Data point term sent to Coder	System	04 Feb 2021 17:59:31
User entered 'Lantus'	Matthew Musikanth (b) (4)	04 Feb 2021 17:58:32

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:58:32

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Type 2 Diabetes'	Matthew Musikanth (b) (4)	04 Feb 2021 17:58:32

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '10'	Matthew Musikanth (b) (4)	04 Feb 2021 17:58:32

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Other (OTHER)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:58:32

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Unit'	Matthew Musikanth (b) (4)	04 Feb 2021 17:58:32

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'once (ONCE)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:58:32

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:11:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	04 Feb 2021 17:58:32

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Other (OTHER)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:58:32

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Injection'	Matthew Musikanth (b) (4)	04 Feb 2021 17:58:32

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:11:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '27 Oct 2020'	Matthew Musikanth (b) (4)	04 Feb 2021 17:58:32

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '0'	Matthew Musikanth (b) (4)	04 Feb 2021 17:58:32

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:58:32

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '27 Oct 2020'	Matthew Musikanth (b) (4)	04 Feb 2021 17:58:32

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:57
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:58:32

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:57
User entered empty.	System	04 Feb 2021 17:58:32

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:57
User entered empty.	System	04 Feb 2021 17:58:32

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:12:57
User entered empty.	System	04 Feb 2021 17:58:32

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:11:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
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)	04 Feb 2021 18:01:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 18:01:51
Data point term sent to Coder	System	04 Feb 2021 18:00:34
User entered 'Lantus'	Matthew Musikanth (b) (4)	04 Feb 2021 17:59:47

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:59:47

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Type 2 Diabetes'	Matthew Musikanth (b) (4)	04 Feb 2021 17:59:47

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '20'	Matthew Musikanth (b) (4)	04 Feb 2021 17:59:47

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Other (OTHER)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:59:47

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'units'	Matthew Musikanth (b) (4)	04 Feb 2021 17:59:47

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'once (ONCE)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:59:47

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:11:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	04 Feb 2021 17:59:47

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Other (OTHER)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:59:47

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Injection'	Matthew Musikanth (b) (4)	04 Feb 2021 17:59:47

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:11:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '28 Oct 2020'	Matthew Musikanth (b) (4)	04 Feb 2021 17:59:47

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '0'	Matthew Musikanth (b) (4)	04 Feb 2021 17:59:47

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:59:47

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '28 Oct 2020'	Matthew Musikanth (b) (4)	04 Feb 2021 17:59:47

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:29
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 17:59:47

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:29
User entered empty.	System	04 Feb 2021 17:59:47

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:29
User entered empty.	System	04 Feb 2021 17:59:47

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:29
User entered empty.	System	04 Feb 2021 17:59:47

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:11:47

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:35
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: BUPIVACAINE;EPINEPHRINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Feb 2021 07:47:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Feb 2021 07:47:47
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:23:38
Data point term sent to Coder	System	17 Feb 2021 23:17:02
DataPoint Un-verified.	Matthew Musikanth	17 Feb 2021 23:16:28
Coding entries removed.	(b) (4)	17 Feb 2021 23:16:28
User entered 'BUPIVACAINE-EPINEPHRINE .5%' reason for change: Data Entry Error	Matthew Musikanth	17 Feb 2021 23:16:28
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:06:10
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: BUPIVACAINE;EPINEPHRINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Feb 2021 09:09:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Feb 2021 09:09:53
Data point term sent to Coder	System	04 Feb 2021 18:01:41
User entered 'Bupivacaine-epinephrine'	Matthew Musikanth	04 Feb 2021 18:00:53

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:35
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:06:10
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 18:00:53

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:35
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:06:10
User entered 'Pinched Nerve'	Matthew Musikanth (b) (4)	04 Feb 2021 18:00:53

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:35
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:06:10
User entered '15'	Matthew Musikanth (b) (4)	04 Feb 2021 18:00:53

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:35
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:06:10
User entered 'mL (mL)'	Matthew Musikanth (b) (4)	04 Feb 2021 18:00:53

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:35
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:06:10
User entered empty.	Matthew Musikanth (b) (4)	04 Feb 2021 18:00:53

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:35
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:06:10
User entered 'once (ONCE)'	Matthew Musikanth (b) (4)	04 Feb 2021 18:00:53

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:11:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:35
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:06:10
User entered empty.	Matthew Musikanth (b) (4)	04 Feb 2021 18:00:53

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:35
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:06:10
User entered 'Other (OTHER)'	Matthew Musikanth (b) (4)	04 Feb 2021 18:00:53

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:35
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:06:10
User entered 'injection'	Matthew Musikanth (b) (4)	04 Feb 2021 18:00:53

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:11:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:35
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:06:10
User entered '28 Oct 2020'	Matthew Musikanth (b) (4)	04 Feb 2021 18:00:53

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:35
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:06:10
User entered '0'	Matthew Musikanth (b) (4)	04 Feb 2021 18:00:53

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:35
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:06:10
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 18:00:53

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:35
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:06:10
User entered '28 Oct 2020'	Matthew Musikanth (b) (4)	04 Feb 2021 18:00:53

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:35
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:06:10
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 18:00:53

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:35
User entered empty.	System	04 Feb 2021 18:00:53

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:35
User entered empty.	System	04 Feb 2021 18:00:53

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:13:35
User entered empty.	System	04 Feb 2021 18:00:53

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:11:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, PRODUCT: CARMELLOSE SODIUM, PRODUCTSYNONYM: REFRESH PLUS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 10:24:25
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 Mar 2021 10:24:25
Data point term sent to Coder	System	04 Feb 2021 18:02:44
User entered 'Refresh Plus Eye Drops .5%'	Matthew Musikanth (b) (4)	04 Feb 2021 18:01:50

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 18:01:50

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Dry Eyes'	Matthew Musikanth	04 Feb 2021 18:01:50
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '1'	Matthew Musikanth (b) (4)	04 Feb 2021 18:01:50

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Other (OTHER)'	Matthew Musikanth	04 Feb 2021 18:01:50
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'drop'	Matthew Musikanth	04 Feb 2021 18:01:50
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'as needed (PRN)'	Matthew Musikanth (b) (4)	04 Feb 2021 18:01:50

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:11:47

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	04 Feb 2021 18:01:50
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Intraocular (INTRAOCULAR)'	Matthew Musikanth (b) (4)	04 Feb 2021 18:01:50

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	04 Feb 2021 18:01:50
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:11:47

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'un UNK 2018'	Matthew Musikanth (b) (4)	04 Feb 2021 18:01:50

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:11:47

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '0'	Matthew Musikanth	04 Feb 2021 18:01:50
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	04 Feb 2021 18:01:50

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	04 Feb 2021 18:01:50
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 18:01:50

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Feb 2021 18:01:50

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Feb 2021 18:01:50

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Feb 2021 18:01:50

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:11:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 18:03:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 18:03:49
Data point term sent to Coder	System	04 Feb 2021 18:02:45
User entered 'Zyrtec'	Matthew Musikanth (b) (4)	04 Feb 2021 18:02:27

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth	04 Feb 2021 18:02:27
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Hayfever'	Matthew Musikanth	04 Feb 2021 18:02:27
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '10'	Matthew Musikanth (b) (4)	04 Feb 2021 18:02:27

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'mg (mg)'	Matthew Musikanth (b) (4)	04 Feb 2021 18:02:27

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	04 Feb 2021 18:02:27

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'as needed (PRN)'	Matthew Musikanth (b) (4)	04 Feb 2021 18:02:27

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:11:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	04 Feb 2021 18:02:27
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	04 Feb 2021 18:02:27

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	04 Feb 2021 18:02:27
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:11:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'un UNK 2009'	Matthew Musikanth (b) (4)	04 Feb 2021 18:02:27

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:11:47

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '0'	Matthew Musikanth (b) (4)	04 Feb 2021 18:02:27

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	04 Feb 2021 18:02:27

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	04 Feb 2021 18:02:27
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 18:02:27

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Feb 2021 18:02:27

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Feb 2021 18:02:27

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Feb 2021 18:02:27

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:11:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: PLANTAGO PSYLLIUM, PRODUCTSYNONYM: PSYLLIUM [PLANTAGO PSYLLIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 08:57:31
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 08:57:31
	(b) (4)	
Data point term sent to Coder	System	04 Feb 2021 18:03:46
User entered 'Psyllium'	Matthew Musikanth	04 Feb 2021 18:03:15
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 04:37:08
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'updated' (Site from DM).	Brenda Grande (b) (4)	05 Mar 2021 17:43:25
User entered 'Yes (Y)' reason for change: Data Entry Error	Brenda Grande (b) (4)	05 Mar 2021 17:43:20
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 05:02:09
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 18:03:15

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Supplement'	Matthew Musikanth (b) (4)	04 Feb 2021 18:03:15

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '1'	Matthew Musikanth (b) (4)	04 Feb 2021 18:03:15

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'capsule (CAPSULE)'	Matthew Musikanth (b) (4)	04 Feb 2021 18:03:15

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	04 Feb 2021 18:03:15

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'twice daily (BID)'	Matthew Musikanth (b) (4)	04 Feb 2021 18:03:15

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:11:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	04 Feb 2021 18:03:15
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Oral (ORAL)'	Matthew Musikanth (b) (4)	04 Feb 2021 18:03:15

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	04 Feb 2021 18:03:15

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:11:47

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '25 Apr 2015'	Matthew Musikanth (b) (4)	04 Feb 2021 18:03:15

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:11:47

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '0'	Matthew Musikanth (b) (4)	04 Feb 2021 18:03:15

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	04 Feb 2021 18:03:15

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	04 Feb 2021 18:03:15
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 18:03:15

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	04 Feb 2021 18:03:15

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Feb 2021 18:03:15

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Feb 2021 18:03:15

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:11:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE, PRODUCT: DICLOFENAC, PRODUCTSYNONYM: VOLTAREN [DICLOFENAC] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Feb 2021 18:05:52
User coded data point as Term Coded data point by	Coder Import (b) (4)	04 Feb 2021 18:05:52
User: Coder System - version WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	04 Feb 2021 18:04:47
User entered 'Voltaren 1%'	Matthew Musikanth (b) (4)	04 Feb 2021 18:04:00

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth	04 Feb 2021 18:04:00
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Bilateral Knee Pain'	Matthew Musikanth	04 Feb 2021 18:04:00
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '1'	Matthew Musikanth (b) (4)	04 Feb 2021 18:04:00

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Other (OTHER)'	Matthew Musikanth (b) (4)	04 Feb 2021 18:04:00

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'application'	Matthew Musikanth (b) (4)	04 Feb 2021 18:04:00

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'as needed (PRN)'	Matthew Musikanth (b) (4)	04 Feb 2021 18:04:00

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:11:47

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	04 Feb 2021 18:04:00
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Topical (TOPICAL)'	Matthew Musikanth (b) (4)	04 Feb 2021 18:04:00

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	04 Feb 2021 18:04:00
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:11:47

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '28 Jan 2012'	Matthew Musikanth (b) (4)	04 Feb 2021 18:04:00

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '0'	Matthew Musikanth (b) (4)	04 Feb 2021 18:04:00

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	04 Feb 2021 18:04:00

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth	04 Feb 2021 18:04:00
	(b) (4)	

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'No (N)'	Matthew Musikanth (b) (4)	04 Feb 2021 18:04:00

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Feb 2021 18:04:00

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Feb 2021 18:04:00

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Feb 2021 18:04:00

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:11:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:08:46
User signature succeeded.	Todd Simmons (b) (4)	28 Apr 2021 21:49:23
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: VARICELLA ZOSTER VACCINES, PRODUCT: VARICELLA ZOSTER VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Apr 2021 21:29:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Apr 2021 21:29:53
Data point term sent to Coder User entered 'Shingles vaccine'	System	26 Apr 2021 21:28:54
	(b) (4), (b) (6)	26 Apr 2021 21:27:54

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:11:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:08:46
User signature succeeded.	Todd Simmons (b) (4)	28 Apr 2021 21:49:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Apr 2021 21:27:54

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:08:46
User signature succeeded.	Todd Simmons (b) (4)	28 Apr 2021 21:49:23
User entered 'Shingles prophylaxis'	(b) (4), (b) (6)	26 Apr 2021 21:27:54

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:11:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:08:46
User signature succeeded.	Todd Simmons (b) (4)	28 Apr 2021 21:49:23
User entered '0.5'	(b) (4), (b) (6)	26 Apr 2021 21:27:54

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:11:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:08:46
User signature succeeded.	Todd Simmons (b) (4)	28 Apr 2021 21:49:23
User entered 'mL (mL)'	(b) (4), (b) (6)	26 Apr 2021 21:27:54

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:11:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:08:46
User signature succeeded.	Todd Simmons (b) (4)	28 Apr 2021 21:49:23
User entered empty.	(b) (4), (b) (6)	26 Apr 2021 21:27:54

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:11:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:08:46
User signature succeeded.	Todd Simmons (b) (4)	28 Apr 2021 21:49:23
User entered 'once (ONCE)'	(b) (4), (b) (6)	26 Apr 2021 21:27:54

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:11:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:08:46
User signature succeeded.	Todd Simmons (b) (4)	28 Apr 2021 21:49:23
User entered empty.	(b) (4), (b) (6)	26 Apr 2021 21:27:54

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:11:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:08:46
User signature succeeded.	Todd Simmons (b) (4)	28 Apr 2021 21:49:23
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	26 Apr 2021 21:27:54

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:11:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:08:46
User signature succeeded.	Todd Simmons (b) (4)	28 Apr 2021 21:49:23
User entered empty.	(b) (4), (b) (6)	26 Apr 2021 21:27:54

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:11:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:08:46
User signature succeeded.	Todd Simmons (b) (4)	28 Apr 2021 21:49:23
User entered '11 Mar 2021'	(b) (4), (b) (6)	26 Apr 2021 21:27:54

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:11:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:08:46
User signature succeeded.	Todd Simmons (b) (4)	28 Apr 2021 21:49:23
User entered '0'	(b) (4), (b) (6)	26 Apr 2021 21:27:54

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:11:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:08:46
User signature succeeded.	Todd Simmons (b) (4)	28 Apr 2021 21:49:23
User entered 'No (N)'	(b) (4), (b) (6)	26 Apr 2021 21:27:54

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:11:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:08:46
User signature succeeded.	Todd Simmons (b) (4)	28 Apr 2021 21:49:23
User entered '11 Mar 2021'	(b) (4), (b) (6)	26 Apr 2021 21:27:54

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:11:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:08:46
User signature succeeded.	Todd Simmons (b) (4)	28 Apr 2021 21:49:23
User entered 'No (N)'	(b) (4), (b) (6)	26 Apr 2021 21:27:54

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:11:47

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:08:46
User entered empty.	System	26 Apr 2021 21:27:54

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:08:46
User entered empty.	System	26 Apr 2021 21:27:54

US3112030

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:11:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:08:46
User entered empty.	System	26 Apr 2021 21:27:54

US3112030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:11:47

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:44:46
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:06:58
User entered 'Yes (Y)'	Matthew Musikanth (b) (4)	13 Jan 2021 23:45:44

US3112030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:11:47

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:07:28
User entered '26 Oct 2020'	Matthew Musikanth	13 Jan 2021 23:46:00
	(b) (4)	

US3112030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:11:47

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:07:28
User entered 'Cervical Decompression'	Matthew Musikanth	13 Jan 2021 23:46:00
	(b) (4)	

US3112030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:07:28
User entered 'Medical History (MH)'	Matthew Musikanth	13 Jan 2021 23:46:00
	(b) (4)	

US3112030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:11:47

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:07:28
User entered empty.	Matthew Musikanth	13 Jan 2021 23:46:00
	(b) (4)	

US3112030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:11:47

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:40
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:07:44
User entered '28 Oct 2020'	Matthew Musikanth (b) (4)	13 Jan 2021 23:46:21

US3112030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:11:47

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:40
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:07:44
User entered 'Corrective back surgery'	Matthew Musikanth (b) (4)	13 Jan 2021 23:46:21

US3112030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:40
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:07:44
User entered 'Adverse Event (AE)'	Matthew Musikanth (b) (4)	13 Jan 2021 23:46:21

US3112030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:11:47

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:40
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 23:07:44
User entered empty.	Matthew Musikanth (b) (4)	13 Jan 2021 23:46:21

US3112030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:11:47

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '11 Dec 2020'	Matthew Musikanth (b) (4)	13 Jan 2021 23:46:41

US3112030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:11:47

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'Tooth extractions x3'	Matthew Musikanth (b) (4)	13 Jan 2021 23:46:41

US3112030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:11:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User closed query 'Per DM CLR: Indication = Medical History, however, there is no corresponding medical condition recorded for this procedure in the MedHistory eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 21:03:03
Query 'Per DM CLR: Indication = Medical History, however, there is no corresponding medical condition recorded for this procedure in the MedHistory eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' answered with 'updated ' (Site from DM).	Brenda Grande (b) (4)	26 Feb 2021 18:18:23
User opened query 'Per DM CLR: Indication = Medical History, however, there is no corresponding medical condition recorded for this procedure in the MedHistory eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 08:03:35
User entered 'Medical History (MH)'	Matthew Musikanth (b) (4)	13 Jan 2021 23:46:41

US3112030

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:11:47

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:44
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered empty.	Matthew Musikanth (b) (4)	13 Jan 2021 23:46:41

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'USA-US062-2021-MRNA-1273-P301000006'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'Yes (Y)'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'No (N)'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'No (N)'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'Yes (Y)'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'No (N)'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'No (N)'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'No (N)'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:31
Un-reviewed for Safety.	System	19 Apr 2021 14:35:59
DataPoint Un-verified.	System	19 Apr 2021 14:35:59
User entered 'Todd'	System	19 Apr 2021 14:35:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:35:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:47
Signature has been broken.	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User entered 'Laurie' reason for change: Data Entry Error	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
Un-reviewed for Safety.	System	17 Mar 2021 20:41:59
DataPoint Un-verified.	System	17 Mar 2021 20:41:59
User entered empty.	System	17 Mar 2021 20:41:59
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'Laurie'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:31
Un-reviewed for Safety.	System	19 Apr 2021 14:35:59
DataPoint Un-verified.	System	19 Apr 2021 14:35:59
User entered 'Simmons'	System	19 Apr 2021 14:35:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:35:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:47
Signature has been broken.	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User entered 'Han-Conrad' reason for change: Data	Matthew Musikanth	16 Apr 2021 17:28:17
Entry Error	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
Un-reviewed for Safety.	System	17 Mar 2021 20:41:59
DataPoint Un-verified.	System	17 Mar 2021 20:41:59
User entered empty.	System	17 Mar 2021 20:41:59
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'Han-Conrad'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:31
Un-reviewed for Safety.	System	19 Apr 2021 14:35:59
DataPoint Un-verified.	System	19 Apr 2021 14:35:59
User entered '9040 Friars Road Suite 540'	System	19 Apr 2021 14:35:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:35:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:47
Signature has been broken.	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User entered '9040 Friars Rd. Suite 540' reason for change: Data Entry Error	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
Un-reviewed for Safety.	System	17 Mar 2021 20:41:59
DataPoint Un-verified.	System	17 Mar 2021 20:41:59
User entered empty.	System	17 Mar 2021 20:41:59
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered '9040 Friars Rd St 540'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:35:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:47
Signature has been broken.	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User entered 'San Diego' reason for change: Data Entry Error	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
Un-reviewed for Safety.	System	17 Mar 2021 20:41:59
DataPoint Un-verified.	System	17 Mar 2021 20:41:59
User entered empty.	System	17 Mar 2021 20:41:59
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'San Diego'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:31
Un-reviewed for Safety.	System	19 Apr 2021 14:35:59
DataPoint Un-verified.	System	19 Apr 2021 14:35:59
User entered 'CA'	System	19 Apr 2021 14:35:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:35:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:47
Signature has been broken.	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User entered 'California' reason for change: Data	Matthew Musikanth	16 Apr 2021 17:28:17
Entry Error	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
Un-reviewed for Safety.	System	17 Mar 2021 20:41:59
DataPoint Un-verified.	System	17 Mar 2021 20:41:59
User entered empty.	System	17 Mar 2021 20:41:59
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'CA'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:35:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:47
Signature has been broken.	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User entered '92108' reason for change: Data Entry Error	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
Un-reviewed for Safety.	System	17 Mar 2021 20:41:59
DataPoint Un-verified.	System	17 Mar 2021 20:41:59
User entered empty.	System	17 Mar 2021 20:41:59
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered '92108'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'US'	System	14 Jan 2021 16:54:50

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	19 Apr 2021 14:35:59
User entered '5'	System	17 Mar 2021 20:41:59
User entered '4'	System	10 Mar 2021 15:34:52
User entered '3'	System	23 Feb 2021 18:12:53
User entered '2'	System	11 Feb 2021 17:19:13
User entered '1'	System	14 Jan 2021 16:54:50

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'USA-US062-2021-MRNA-1273-P301000006'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'Yes (Y)'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'No (N)'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'No (N)'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'Yes (Y)'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'No (N)'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'No (N)'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'No (N)'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:31
Un-reviewed for Safety.	System	19 Apr 2021 14:35:59
DataPoint Un-verified.	System	19 Apr 2021 14:35:59
User entered 'Todd'	System	19 Apr 2021 14:35:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:35:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:47
Signature has been broken.	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User entered 'Laurie' reason for change: Data Entry Error	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
Un-reviewed for Safety.	System	17 Mar 2021 20:41:59
DataPoint Un-verified.	System	17 Mar 2021 20:41:59
User entered empty.	System	17 Mar 2021 20:41:59
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'Laurie'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:31
Un-reviewed for Safety.	System	19 Apr 2021 14:35:59
DataPoint Un-verified.	System	19 Apr 2021 14:35:59
User entered 'Simmons'	System	19 Apr 2021 14:35:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:35:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:47
Signature has been broken.	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User entered 'Han-Conrad' reason for change: Data	Matthew Musikanth	16 Apr 2021 17:28:17
Entry Error	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
Un-reviewed for Safety.	System	17 Mar 2021 20:41:59
DataPoint Un-verified.	System	17 Mar 2021 20:41:59
User entered empty.	System	17 Mar 2021 20:41:59
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'Han-Conrad'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:31
Un-reviewed for Safety.	System	19 Apr 2021 14:35:59
DataPoint Un-verified.	System	19 Apr 2021 14:35:59
User entered '9040 Friars Road Suite 540'	System	19 Apr 2021 14:35:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:35:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:47
Signature has been broken.	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User entered '9040 Friars Rd. Suite 540' reason for change: Data Entry Error	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
Un-reviewed for Safety.	System	17 Mar 2021 20:41:59
DataPoint Un-verified.	System	17 Mar 2021 20:41:59
User entered empty.	System	17 Mar 2021 20:41:59
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered '9040 Friars Rd St 540'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:35:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:47
Signature has been broken.	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User entered 'San Diego' reason for change: Data Entry Error	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
Un-reviewed for Safety.	System	17 Mar 2021 20:41:59
DataPoint Un-verified.	System	17 Mar 2021 20:41:59
User entered empty.	System	17 Mar 2021 20:41:59
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'San Diego'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:31
Un-reviewed for Safety.	System	19 Apr 2021 14:35:59
DataPoint Un-verified.	System	19 Apr 2021 14:35:59
User entered 'CA'	System	19 Apr 2021 14:35:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:35:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:47
Signature has been broken.	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User entered 'California' reason for change: Data	Matthew Musikanth	16 Apr 2021 17:28:17
Entry Error	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
Un-reviewed for Safety.	System	17 Mar 2021 20:41:59
DataPoint Un-verified.	System	17 Mar 2021 20:41:59
User entered empty.	System	17 Mar 2021 20:41:59
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'CA'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:35:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:47
Signature has been broken.	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User entered '92108' reason for change: Data Entry Error	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
Un-reviewed for Safety.	System	17 Mar 2021 20:41:59
DataPoint Un-verified.	System	17 Mar 2021 20:41:59
User entered empty.	System	17 Mar 2021 20:41:59
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered '92108'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'US'	System	14 Jan 2021 16:54:50

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	19 Apr 2021 14:35:59
User entered '5'	System	17 Mar 2021 20:41:59
User entered '4'	System	10 Mar 2021 15:34:52
User entered '3'	System	23 Feb 2021 18:12:53
User entered '2'	System	11 Feb 2021 17:19:13
User entered '1'	System	14 Jan 2021 16:54:50

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:11:47

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
User entered '14/Jan/2021 11:54'	System	14 Jan 2021 16:54:50

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:11:47

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'I'	(b) (4), (b) (6)	14 Jan 2021 16:54:50

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'USA-US062-2021-MRNA-1273-P301000006'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

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Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'Yes (Y)'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'No (N)'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'No (N)'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'Yes (Y)'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'No (N)'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'No (N)'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'No (N)'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:31
Un-reviewed for Safety.	System	19 Apr 2021 14:35:59
DataPoint Un-verified.	System	19 Apr 2021 14:35:59
User entered 'Todd'	System	19 Apr 2021 14:35:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:35:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:47
Signature has been broken.	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User entered 'Laurie' reason for change: Data Entry Error	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
Un-reviewed for Safety.	System	17 Mar 2021 20:41:59
DataPoint Un-verified.	System	17 Mar 2021 20:41:59
User entered empty.	System	17 Mar 2021 20:41:59
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'Laurie'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:31
Un-reviewed for Safety.	System	19 Apr 2021 14:35:59
DataPoint Un-verified.	System	19 Apr 2021 14:35:59
User entered 'Simmons'	System	19 Apr 2021 14:35:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:35:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:47
Signature has been broken.	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User entered 'Han-Conrad' reason for change: Data	Matthew Musikanth	16 Apr 2021 17:28:17
Entry Error	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
Un-reviewed for Safety.	System	17 Mar 2021 20:41:59
DataPoint Un-verified.	System	17 Mar 2021 20:41:59
User entered empty.	System	17 Mar 2021 20:41:59
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'Han-Conrad'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:31
Un-reviewed for Safety.	System	19 Apr 2021 14:35:59
DataPoint Un-verified.	System	19 Apr 2021 14:35:59
User entered '9040 Friars Road Suite 540'	System	19 Apr 2021 14:35:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:35:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:47
Signature has been broken.	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User entered '9040 Friars Rd. Suite 540' reason for change: Data Entry Error	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
Un-reviewed for Safety.	System	17 Mar 2021 20:41:59
DataPoint Un-verified.	System	17 Mar 2021 20:41:59
User entered empty.	System	17 Mar 2021 20:41:59
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered '9040 Friars Rd St 540'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:35:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:47
Signature has been broken.	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User entered 'San Diego' reason for change: Data Entry Error	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
Un-reviewed for Safety.	System	17 Mar 2021 20:41:59
DataPoint Un-verified.	System	17 Mar 2021 20:41:59
User entered empty.	System	17 Mar 2021 20:41:59
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'San Diego'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:31
Un-reviewed for Safety.	System	19 Apr 2021 14:35:59
DataPoint Un-verified.	System	19 Apr 2021 14:35:59
User entered 'CA'	System	19 Apr 2021 14:35:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:35:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:47
Signature has been broken.	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User entered 'California' reason for change: Data	Matthew Musikanth	16 Apr 2021 17:28:17
Entry Error	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
Un-reviewed for Safety.	System	17 Mar 2021 20:41:59
DataPoint Un-verified.	System	17 Mar 2021 20:41:59
User entered empty.	System	17 Mar 2021 20:41:59
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'CA'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:35:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:47
Signature has been broken.	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User entered '92108' reason for change: Data Entry Error	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
Un-reviewed for Safety.	System	17 Mar 2021 20:41:59
DataPoint Un-verified.	System	17 Mar 2021 20:41:59
User entered empty.	System	17 Mar 2021 20:41:59
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered '92108'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'US'	System	14 Jan 2021 16:54:50

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	19 Apr 2021 14:35:59
User entered '5'	System	17 Mar 2021 20:41:59
User entered '4'	System	10 Mar 2021 15:34:52
User entered '3'	System	23 Feb 2021 18:12:53
User entered '2'	System	11 Feb 2021 17:19:13
User entered '1'	System	14 Jan 2021 16:54:50

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:11:47

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
User entered '11/Feb/2021 11:19'	System	11 Feb 2021 17:19:13

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:11:47

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 18:12:22
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
User entered 'I'	(b) (4), (b) (6)	11 Feb 2021 17:19:13

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'USA-US062-2021-MRNA-1273-P301000006'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'Yes (Y)'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'No (N)'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'No (N)'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'Yes (Y)'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'No (N)'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'No (N)'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'No (N)'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:31
Un-reviewed for Safety.	System	19 Apr 2021 14:35:59
DataPoint Un-verified.	System	19 Apr 2021 14:35:59
User entered 'Todd'	System	19 Apr 2021 14:35:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:35:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:47
Signature has been broken.	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User entered 'Laurie' reason for change: Data Entry Error	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
Un-reviewed for Safety.	System	17 Mar 2021 20:41:59
DataPoint Un-verified.	System	17 Mar 2021 20:41:59
User entered empty.	System	17 Mar 2021 20:41:59
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'Laurie'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:31
Un-reviewed for Safety.	System	19 Apr 2021 14:35:59
DataPoint Un-verified.	System	19 Apr 2021 14:35:59
User entered 'Simmons'	System	19 Apr 2021 14:35:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:35:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:47
Signature has been broken.	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User entered 'Han-Conrad' reason for change: Data	Matthew Musikanth	16 Apr 2021 17:28:17
Entry Error	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
Un-reviewed for Safety.	System	17 Mar 2021 20:41:59
DataPoint Un-verified.	System	17 Mar 2021 20:41:59
User entered empty.	System	17 Mar 2021 20:41:59
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'Han-Conrad'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:31
Un-reviewed for Safety.	System	19 Apr 2021 14:35:59
DataPoint Un-verified.	System	19 Apr 2021 14:35:59
User entered '9040 Friars Road Suite 540'	System	19 Apr 2021 14:35:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:35:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:47
Signature has been broken.	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User entered '9040 Friars Rd. Suite 540' reason for change: Data Entry Error	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
Un-reviewed for Safety.	System	17 Mar 2021 20:41:59
DataPoint Un-verified.	System	17 Mar 2021 20:41:59
User entered empty.	System	17 Mar 2021 20:41:59
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered '9040 Friars Rd St 540'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:35:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:47
Signature has been broken.	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User entered 'San Diego' reason for change: Data Entry Error	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
Un-reviewed for Safety.	System	17 Mar 2021 20:41:59
DataPoint Un-verified.	System	17 Mar 2021 20:41:59
User entered empty.	System	17 Mar 2021 20:41:59
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'San Diego'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:31
Un-reviewed for Safety.	System	19 Apr 2021 14:35:59
DataPoint Un-verified.	System	19 Apr 2021 14:35:59
User entered 'CA'	System	19 Apr 2021 14:35:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:35:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:47
Signature has been broken.	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User entered 'California' reason for change: Data	Matthew Musikanth	16 Apr 2021 17:28:17
Entry Error	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
Un-reviewed for Safety.	System	17 Mar 2021 20:41:59
DataPoint Un-verified.	System	17 Mar 2021 20:41:59
User entered empty.	System	17 Mar 2021 20:41:59
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'CA'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:35:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:47
Signature has been broken.	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User entered '92108' reason for change: Data Entry Error	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
Un-reviewed for Safety.	System	17 Mar 2021 20:41:59
DataPoint Un-verified.	System	17 Mar 2021 20:41:59
User entered empty.	System	17 Mar 2021 20:41:59
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered '92108'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'US'	System	14 Jan 2021 16:54:50

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	19 Apr 2021 14:35:59
User entered '5'	System	17 Mar 2021 20:41:59
User entered '4'	System	10 Mar 2021 15:34:52
User entered '3'	System	23 Feb 2021 18:12:53
User entered '2'	System	11 Feb 2021 17:19:13
User entered '1'	System	14 Jan 2021 16:54:50

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:11:47

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '23/Feb/2021 13:12'	System	23 Feb 2021 18:12:53

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:11:47

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 15:34:38
User entered '1' reason for change: New Information	(b) (4), (b) (6)	23 Feb 2021 18:12:53
User entered '0'	(b) (4), (b) (6)	23 Feb 2021 18:12:38

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'USA-US062-2021-MRNA-1273-P301000006'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'Yes (Y)'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'No (N)'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'No (N)'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'Yes (Y)'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'No (N)'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'No (N)'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'No (N)'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:31
Un-reviewed for Safety.	System	19 Apr 2021 14:35:59
DataPoint Un-verified.	System	19 Apr 2021 14:35:59
User entered 'Todd'	System	19 Apr 2021 14:35:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:35:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:47
Signature has been broken.	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User entered 'Laurie' reason for change: Data Entry Error	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
Un-reviewed for Safety.	System	17 Mar 2021 20:41:59
DataPoint Un-verified.	System	17 Mar 2021 20:41:59
User entered empty.	System	17 Mar 2021 20:41:59
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'Laurie'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:31
Un-reviewed for Safety.	System	19 Apr 2021 14:35:59
DataPoint Un-verified.	System	19 Apr 2021 14:35:59
User entered 'Simmons'	System	19 Apr 2021 14:35:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:35:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:47
Signature has been broken.	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User entered 'Han-Conrad' reason for change: Data	Matthew Musikanth	16 Apr 2021 17:28:17
Entry Error	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
Un-reviewed for Safety.	System	17 Mar 2021 20:41:59
DataPoint Un-verified.	System	17 Mar 2021 20:41:59
User entered empty.	System	17 Mar 2021 20:41:59
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'Han-Conrad'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:31
Un-reviewed for Safety.	System	19 Apr 2021 14:35:59
DataPoint Un-verified.	System	19 Apr 2021 14:35:59
User entered '9040 Friars Road Suite 540'	System	19 Apr 2021 14:35:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:35:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:47
Signature has been broken.	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User entered '9040 Friars Rd. Suite 540' reason for change: Data Entry Error	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
Un-reviewed for Safety.	System	17 Mar 2021 20:41:59
DataPoint Un-verified.	System	17 Mar 2021 20:41:59
User entered empty.	System	17 Mar 2021 20:41:59
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered '9040 Friars Rd St 540'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:35:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:47
Signature has been broken.	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User entered 'San Diego' reason for change: Data Entry Error	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
Un-reviewed for Safety.	System	17 Mar 2021 20:41:59
DataPoint Un-verified.	System	17 Mar 2021 20:41:59
User entered empty.	System	17 Mar 2021 20:41:59
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'San Diego'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:31
Un-reviewed for Safety.	System	19 Apr 2021 14:35:59
DataPoint Un-verified.	System	19 Apr 2021 14:35:59
User entered 'CA'	System	19 Apr 2021 14:35:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:35:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:47
Signature has been broken.	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User entered 'California' reason for change: Data	Matthew Musikanth	16 Apr 2021 17:28:17
Entry Error	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
Un-reviewed for Safety.	System	17 Mar 2021 20:41:59
DataPoint Un-verified.	System	17 Mar 2021 20:41:59
User entered empty.	System	17 Mar 2021 20:41:59
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'CA'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:35:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:47
Signature has been broken.	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User entered '92108' reason for change: Data Entry Error	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
Un-reviewed for Safety.	System	17 Mar 2021 20:41:59
DataPoint Un-verified.	System	17 Mar 2021 20:41:59
User entered empty.	System	17 Mar 2021 20:41:59
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered '92108'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'US'	System	14 Jan 2021 16:54:50

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	19 Apr 2021 14:35:59
User entered '5'	System	17 Mar 2021 20:41:59
User entered '4'	System	10 Mar 2021 15:34:52
User entered '3'	System	23 Feb 2021 18:12:53
User entered '2'	System	11 Feb 2021 17:19:13
User entered '1'	System	14 Jan 2021 16:54:50

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:11:47

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '10/Mar/2021 09:34'	System	10 Mar 2021 15:34:52

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:11:47

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
Reviewed for Safety.	(b) (4), (b) (6)	17 Mar 2021 20:41:35
User entered 'I'	(b) (4), (b) (6)	10 Mar 2021 15:34:52

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'USA-US062-2021-MRNA-1273-P301000006'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'Yes (Y)'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'No (N)'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'No (N)'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'Yes (Y)'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'No (N)'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'No (N)'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'No (N)'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:31
Un-reviewed for Safety.	System	19 Apr 2021 14:35:59
DataPoint Un-verified.	System	19 Apr 2021 14:35:59
User entered 'Todd'	System	19 Apr 2021 14:35:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:35:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:47
Signature has been broken.	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User entered 'Laurie' reason for change: Data Entry Error	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
Un-reviewed for Safety.	System	17 Mar 2021 20:41:59
DataPoint Un-verified.	System	17 Mar 2021 20:41:59
User entered empty.	System	17 Mar 2021 20:41:59
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'Laurie'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:31
Un-reviewed for Safety.	System	19 Apr 2021 14:35:59
DataPoint Un-verified.	System	19 Apr 2021 14:35:59
User entered 'Simmons'	System	19 Apr 2021 14:35:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:35:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:47
Signature has been broken.	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User entered 'Han-Conrad' reason for change: Data	Matthew Musikanth	16 Apr 2021 17:28:17
Entry Error	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
Un-reviewed for Safety.	System	17 Mar 2021 20:41:59
DataPoint Un-verified.	System	17 Mar 2021 20:41:59
User entered empty.	System	17 Mar 2021 20:41:59
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'Han-Conrad'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:31
Un-reviewed for Safety.	System	19 Apr 2021 14:35:59
DataPoint Un-verified.	System	19 Apr 2021 14:35:59
User entered '9040 Friars Road Suite 540'	System	19 Apr 2021 14:35:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:35:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:47
Signature has been broken.	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User entered '9040 Friars Rd. Suite 540' reason for change: Data Entry Error	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
Un-reviewed for Safety.	System	17 Mar 2021 20:41:59
DataPoint Un-verified.	System	17 Mar 2021 20:41:59
User entered empty.	System	17 Mar 2021 20:41:59
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered '9040 Friars Rd St 540'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:35:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:47
Signature has been broken.	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User entered 'San Diego' reason for change: Data Entry Error	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
Un-reviewed for Safety.	System	17 Mar 2021 20:41:59
DataPoint Un-verified.	System	17 Mar 2021 20:41:59
User entered empty.	System	17 Mar 2021 20:41:59
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'San Diego'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:31
Un-reviewed for Safety.	System	19 Apr 2021 14:35:59
DataPoint Un-verified.	System	19 Apr 2021 14:35:59
User entered 'CA'	System	19 Apr 2021 14:35:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:35:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:47
Signature has been broken.	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User entered 'California' reason for change: Data	Matthew Musikanth	16 Apr 2021 17:28:17
Entry Error	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
Un-reviewed for Safety.	System	17 Mar 2021 20:41:59
DataPoint Un-verified.	System	17 Mar 2021 20:41:59
User entered empty.	System	17 Mar 2021 20:41:59
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'CA'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:35:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:47
Signature has been broken.	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User entered '92108' reason for change: Data Entry Error	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
Un-reviewed for Safety.	System	17 Mar 2021 20:41:59
DataPoint Un-verified.	System	17 Mar 2021 20:41:59
User entered empty.	System	17 Mar 2021 20:41:59
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered '92108'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'US'	System	14 Jan 2021 16:54:50

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	19 Apr 2021 14:35:59
User entered '5'	System	17 Mar 2021 20:41:59
User entered '4'	System	10 Mar 2021 15:34:52
User entered '3'	System	23 Feb 2021 18:12:53
User entered '2'	System	11 Feb 2021 17:19:13
User entered '1'	System	14 Jan 2021 16:54:50

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:11:47

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered '17/Mar/2021 15:41'	System	17 Mar 2021 20:41:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:11:47

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:35:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:47
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
User entered 'I'	(b) (4), (b) (6)	17 Mar 2021 20:41:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'USA-US062-2021-MRNA-1273-P301000006'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

Serious

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'Yes (Y)'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'No (N)'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'No (N)'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'Yes (Y)'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'No (N)'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'No (N)'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'No (N)'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:31
Un-reviewed for Safety.	System	19 Apr 2021 14:35:59
DataPoint Un-verified.	System	19 Apr 2021 14:35:59
User entered 'Todd'	System	19 Apr 2021 14:35:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:35:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:47
Signature has been broken.	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User entered 'Laurie' reason for change: Data Entry Error	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
Un-reviewed for Safety.	System	17 Mar 2021 20:41:59
DataPoint Un-verified.	System	17 Mar 2021 20:41:59
User entered empty.	System	17 Mar 2021 20:41:59
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'Laurie'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:31
Un-reviewed for Safety.	System	19 Apr 2021 14:35:59
DataPoint Un-verified.	System	19 Apr 2021 14:35:59
User entered 'Simmons'	System	19 Apr 2021 14:35:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:35:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:47
Signature has been broken.	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User entered 'Han-Conrad' reason for change: Data	Matthew Musikanth	16 Apr 2021 17:28:17
Entry Error	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
Un-reviewed for Safety.	System	17 Mar 2021 20:41:59
DataPoint Un-verified.	System	17 Mar 2021 20:41:59
User entered empty.	System	17 Mar 2021 20:41:59
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'Han-Conrad'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:31
Un-reviewed for Safety.	System	19 Apr 2021 14:35:59
DataPoint Un-verified.	System	19 Apr 2021 14:35:59
User entered '9040 Friars Road Suite 540'	System	19 Apr 2021 14:35:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:35:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:47
Signature has been broken.	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User entered '9040 Friars Rd. Suite 540' reason for change: Data Entry Error	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
Un-reviewed for Safety.	System	17 Mar 2021 20:41:59
DataPoint Un-verified.	System	17 Mar 2021 20:41:59
User entered empty.	System	17 Mar 2021 20:41:59
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered '9040 Friars Rd St 540'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:35:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:47
Signature has been broken.	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User entered 'San Diego' reason for change: Data Entry Error	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
Un-reviewed for Safety.	System	17 Mar 2021 20:41:59
DataPoint Un-verified.	System	17 Mar 2021 20:41:59
User entered empty.	System	17 Mar 2021 20:41:59
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'San Diego'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:31
Un-reviewed for Safety.	System	19 Apr 2021 14:35:59
DataPoint Un-verified.	System	19 Apr 2021 14:35:59
User entered 'CA'	System	19 Apr 2021 14:35:59
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:35:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:47
Signature has been broken.	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User entered 'California' reason for change: Data	Matthew Musikanth	16 Apr 2021 17:28:17
Entry Error	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
Un-reviewed for Safety.	System	17 Mar 2021 20:41:59
DataPoint Un-verified.	System	17 Mar 2021 20:41:59
User entered empty.	System	17 Mar 2021 20:41:59
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'CA'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 14:35:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:55:47
Signature has been broken.	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User entered '92108' reason for change: Data Entry Error	Matthew Musikanth	16 Apr 2021 17:28:17
	(b) (4)	
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
Un-reviewed for Safety.	System	17 Mar 2021 20:41:59
DataPoint Un-verified.	System	17 Mar 2021 20:41:59
User entered empty.	System	17 Mar 2021 20:41:59
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered '92108'	System	14 Jan 2021 16:53:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	02 Apr 2021 20:23:05
DataPoint Verified.	(b) (4), (b) (6)	17 Feb 2021 22:38:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Jan 2021 16:56:46
User entered 'US'	System	14 Jan 2021 16:54:50

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 15:11:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	19 Apr 2021 14:35:59
User entered '5'	System	17 Mar 2021 20:41:59
User entered '4'	System	10 Mar 2021 15:34:52
User entered '3'	System	23 Feb 2021 18:12:53
User entered '2'	System	11 Feb 2021 17:19:13
User entered '1'	System	14 Jan 2021 16:54:50

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:11:47

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:31
User entered '19/Apr/2021 09:35'	System	19 Apr 2021 14:35:59

US3112030

Folder: SAE USA-US062-2021-MRNA-1273-P301000006

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:11:47

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Todd Simmons (b) (4)	23 Apr 2021 21:01:31
User entered 'I'	(b) (4), (b) (6)	19 Apr 2021 14:35:59