

US3172250 (Prod: Suncoast Research Group LLC - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:34:09

All time stamps listed in this document are displayed in GMT

US3172250

Form: Participant Creation

Data signed: (b) (4) 17 Feb 2021 13:15:39

Generated On: 09 Jun 2021 15:34:09

Participant ID

US3172250

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

US3172250

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:15:48

Generated On: 09 Jun 2021 15:34:09

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

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

Folder OID	SCRN
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US3172250

Folder: Screening

Form: Demographics

Data signed: (b) (4) 17 Feb 2021 13:15:48

Generated On: 09 Jun 2021 15:34:09

Date of Birth (MMM yyyy)	(b) (6) 1961
Age	59
Age Units	YEARS
Age (Derived)	59
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3172250

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 17 Feb 2021 13:15:48

Generated On: 09 Jun 2021 15:34:09

Date of Informed Consent (*dd MMM yyyy*) 20 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1	<input checked="" type="radio"/>
Amendment 2	<input type="radio"/>
Amendment 3	<input type="radio"/>
Amendment 4	<input type="radio"/>
Amendment 5	<input type="radio"/>

Was participant enrolled in the study?

Yes	<input checked="" type="radio"/>
No	<input type="radio"/>

If No, indicate reason for screen fail

Withdrew Consent	<input type="radio"/>
Inclusion/Exclusion	<input type="radio"/>
Cohort Full	<input type="radio"/>
Other	<input type="radio"/>

If reason for screen fail is Other, specify _____

Was this participant screened previously?

Yes	<input type="radio"/>
No	<input checked="" type="radio"/>

If Yes, previous participant number _____

Enrollment Trigger 1

US3172250

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 17 Feb 2021 13:15:48

Generated On: 09 Jun 2021 15:34:09

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3172250

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 17 Feb 2021 13:15:48

Generated On: 09 Jun 2021 15:34:09

Were any significant conditions reported?

Yes ☒
No ☐

US3172250

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 28 Apr 2021 07:34:10

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 28 Apr 2021 07:34:10

Generated On: 09 Jun 2021 15:34:09

Condition	HYPERTENSION MILD
Start date (dd MMM yyyy)	UN UNK 1986
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1986
Start Year (derived)	1986
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3172250

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 28 Apr 2021 07:34:10

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 28 Apr 2021 07:34:10

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 28 Apr 2021 07:34:10

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 28 Apr 2021 07:34:10

Generated On: 09 Jun 2021 15:34:09

Condition	BACK PAIN
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)	_____

US3172250

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 28 Apr 2021 07:34:10

Generated On: 09 Jun 2021 15:34:09

Condition	CONGENITAL ECTRODOCTYLIA
Start date (dd MMM yyyy)	(b) (6) 1961
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)	(b) (6) 1961
Start Year (derived)	1961
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3172250

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 28 Apr 2021 07:34:10

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 28 Apr 2021 07:34:10

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 28 Apr 2021 07:34:10

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 28 Apr 2021 07:34:10

Generated On: 09 Jun 2021 15:34:09

Condition	POST AUTOMATED IMPLANTABLE CARDIOVERTER DEFIBRILLATOR CONGESTIVE HEART FAILURE
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	

US3172250

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 28 Apr 2021 07:34:10

Generated On: 09 Jun 2021 15:34:09

Condition	BIVENTRICULOR DUAL CHAMBER
Start date (dd MMM yyyy)	04 DEC 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)	DEC 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

US3172250

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 28 Apr 2021 07:34:10

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 28 Apr 2021 07:34:10

Generated On: 09 Jun 2021 15:34:09

Condition	PAROXYSMAL ATRIAL FIBRILLATION
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	

US3172250

Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 28 Apr 2021 07:34:10

Generated On: 09 Jun 2021 15:34:09

Condition	ISCHEMIC CARDIOMYOPATHY
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3172250

Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 28 Apr 2021 07:34:10

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 28 Apr 2021 07:34:10

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 28 Apr 2021 07:34:10

Generated On: 09 Jun 2021 15:34:09

Condition	CEREBROVASCULAR ACCIDENT
Start date (dd MMM yyyy)	04 JUL 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	04 JUL 2020
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JUL 2020
Stop Year (derived)	2020

US3172250

Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 28 Apr 2021 07:34:10

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 28 Apr 2021 07:34:10

Generated On: 09 Jun 2021 15:34:09

Condition	SENSORIAL DIABETIC PERIPHERAL NEUROPATHY
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)	

US3172250

Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 28 Apr 2021 07:34:10

Generated On: 09 Jun 2021 15:34:09

Condition	STROKE VS. TRANSIENT ISCHEMIC ATTACKS
Start date (dd MMM yyyy)	UN APR 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN APR 2020
Stop date completely unknown	False
Start Month and Year (derived)	APR 2020
Start Year (derived)	2020
Stop Month and Year (derived)	APR 2020
Stop Year (derived)	2020

US3172250

Folder: Screening

Form: Medical History (22)

Data signed: (b) (4) 28 Apr 2021 07:34:10

Generated On: 09 Jun 2021 15:34:09

Condition	PENILE IMPLANT INFECTION AND REMOVAL OF PROSTHESIS
Start date (dd MMM yyyy)	19 MAY 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	30 JUN 2020
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JUN 2020
Stop Year (derived)	2020

US3172250

Folder: Screening

Form: Medical History (23)

Data signed: (b) (4) 28 Apr 2021 07:34:10

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: Screening

Form: Medical History (24)

Data signed: (b) (4) 28 Apr 2021 07:34:10

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: Screening

Form: Medical History (25)

Data signed: (b) (4) 28 Apr 2021 07:34:10

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: Screening

Form: Medical History (26)

Data signed: (b) (4) 28 Apr 2021 07:34:10

Generated On: 09 Jun 2021 15:34:09

Condition	DEFIBRILLATOR
Start date (dd MMM yyyy)	04 DEC 2008
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)	04 DEC 2016
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2008
Start Year (derived)	2008
Stop Month and Year (derived)	DEC 2016
Stop Year (derived)	2016

US3172250

Folder: Screening

Form: Medical History (27)

Data signed: (b) (4) 28 Apr 2021 07:34:10

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 13:15:48

Generated On: 09 Jun 2021 15:34:09

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 AUG 2020
Time of assessment (00:00-23:59)	11:43 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 11:43
Height (xxx.x)	163.0 cm
Weight (xxx.x)	117.0 kg
BMI (xxx.x)	44.03628 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3172250

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 13:15:48

Generated On: 09 Jun 2021 15:34:09

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.

US3172250

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 17 Feb 2021 13:15:48

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 17 Feb 2021 13:15:48

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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)	True
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

US3172250

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:15:48

Generated On: 09 Jun 2021 15:34:09

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

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

Folder OID	VISIT1
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US3172250

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 17 Feb 2021 13:15:48

Generated On: 09 Jun 2021 15:34:09

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

What was the participant's randomization number? 144372

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 ☒

US3172250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 17 Feb 2021 13:15:48

Generated On: 09 Jun 2021 15:34:09

Height	ND - Not Done
Weight	ND - Not Done

US3172250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 13:15:48

Generated On: 09 Jun 2021 15:34:09

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 AUG 2020
Time of assessment (00:00-23:59)	11:43 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 11:43
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3172250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 13:15:48

Generated On: 09 Jun 2021 15:34:09

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)	20 AUG 2020
Time of assessment (00:00-23:59)	16:04 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 16:04
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3172250

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 13:15:48

Generated On: 09 Jun 2021 15:34:09

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 AUG 2020

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

US3172250

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 17 Feb 2021 13:15:48

Generated On: 09 Jun 2021 15:34:09

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 15:34 (24 HR)

Treatment Date and Time (derived) 20 AUG 2020 15:34

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

US3172250

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 13:15:48

Generated On: 09 Jun 2021 15:34:09

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

Collection date (dd MMM yyyy)	20 AUG 2020
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Collection time (00:00-23:59)	14:42 (24 HR)
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Collection date and time (derived)	20 AUG 2020 14:42
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US3172250

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 17 Feb 2021 13:15:48

Generated On: 09 Jun 2021 15:34:09

Collection date (dd MMM yyyy)			20 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:38	20 AUG 2020 14:38
Nasopharyngeal Swab 2	No		

US3172250

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:15:48

Generated On: 09 Jun 2021 15:34:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

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

20 AUG 2020 16:16

PC Open Date & Time

20 AUG 2020 15:54

PC Close Date & Time

20 AUG 2020 18:24

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.0 °F

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

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

To **TREAT** pain or fever that has already occurred False

To **PREVENT** pain or fever from occurring True

PC Time Stamp 20 AUG 2020 20:20

PC Open Date & Time 20 AUG 2020 19:19

PC Close Date & Time 21 AUG 2020 11:59

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:34:09

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

97.8 °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

21 AUG 2020 16:07

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 14:45

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 12:31

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 13:22

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

25 AUG 2020 13:27

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 12:10

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

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

20 AUG 2020 16:17

PC Open Date & Time

20 AUG 2020 15:54

PC Close Date & Time

20 AUG 2020 18:24

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 20:21

PC Open Date & Time

20 AUG 2020 19:19

PC Close Date & Time

21 AUG 2020 11:59

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 AUG 2020 16:07

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 AUG 2020 14:45

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 AUG 2020 12:31

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 AUG 2020 13:23

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 13:28

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 12:10

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

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 ☐

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 16:17
PC Open Date & Time	20 AUG 2020 15:54
PC Close Date & Time	20 AUG 2020 18:24

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

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 ☐

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 20:22
PC Open Date & Time	20 AUG 2020 19:19
PC Close Date & Time	21 AUG 2020 11:59

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:09

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 ☒

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:09

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 16:08
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:09

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

70 of 4086

EAB) (1725)

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:09

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 14:46
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:09

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 ☒

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:09

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 12:32
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

74 of 4086

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:09

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 13:24
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:09

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

EAB) (1725)

76 of 4086

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:09

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 13:28
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:09

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)

78 of 4086

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:15:48

Generated On: 09 Jun 2021 15:34:09

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3172250

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:15:48

Generated On: 09 Jun 2021 15:34:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172250

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:15:48

Generated On: 09 Jun 2021 15:34:09

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 04 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3172250

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:15:48

Generated On: 09 Jun 2021 15:34:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172250

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:15:48

Generated On: 09 Jun 2021 15:34:09

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 10 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3172250

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:15:48

Generated On: 09 Jun 2021 15:34:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172250

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:15:48

Generated On: 09 Jun 2021 15:34:09

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

Visit date (dd MMM yyyy)	18 SEP 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT2
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US3172250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 13:15:48

Generated On: 09 Jun 2021 15:34:09

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 SEP 2020
Time of assessment (00:00-23:59)	09:55 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 09:55
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3172250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 13:15:48

Generated On: 09 Jun 2021 15:34:09

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	18 SEP 2020
Time of assessment (00:00-23:59)	12:43 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 12:43
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3172250

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 13:15:48

Generated On: 09 Jun 2021 15:34:09

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 SEP 2020

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

US3172250

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 17 Feb 2021 13:15:48

Generated On: 09 Jun 2021 15:34:09

Was study treatment given? Yes ☒
No ☐

If No, reason not given

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 12:13 (24 HR)

Treatment Date and Time (derived) 18 SEP 2020 12:13

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

US3172250

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 13:15:48

Generated On: 09 Jun 2021 15:34:09

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 18 SEP 2020

Collection time (00:00-23:59) 11:50 (24 HR)

Collection date and time (derived) 18 SEP 2020 11:50

US3172250

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 17 Feb 2021 13:15:48

Generated On: 09 Jun 2021 15:34:09

Collection date (dd MMM yyyy)			18 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:46	18 SEP 2020 11:46
Nasopharyngeal Swab 2	No		

US3172250

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:15:48

Generated On: 09 Jun 2021 15:34:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

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

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 12:44

PC Open Date & Time

18 SEP 2020 12:33

PC Close Date & Time

18 SEP 2020 15:03

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

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 98.3 °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	18 SEP 2020 21:09
PC Open Date & Time	18 SEP 2020 15:58
PC Close Date & Time	19 SEP 2020 11:59

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:34:09

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

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 21:31

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:34:09

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

20 SEP 2020 21:40

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:34:09

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

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

21 SEP 2020 14:12

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °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

22 SEP 2020 13:34

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:34:09

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

23 SEP 2020 12:04

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

24 SEP 2020 13:07

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 12:45

PC Open Date & Time

18 SEP 2020 12:33

PC Close Date & Time

18 SEP 2020 15:03

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 21:10

PC Open Date & Time

18 SEP 2020 15:58

PC Close Date & Time

19 SEP 2020 11:59

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 21:32

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 SEP 2020 21:40

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 14:12

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 13:34

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 12:05

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 SEP 2020 13:07

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

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 ☐

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

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

No ☒

Yes ☐

PC Time stamp	18 SEP 2020 12:45
PC Open Date & Time	18 SEP 2020 12:33
PC Close Date & Time	18 SEP 2020 15:03

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

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 ☐

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

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

No ☒

Yes ☐

PC Time stamp	18 SEP 2020 21:10
PC Open Date & Time	18 SEP 2020 15:58
PC Close Date & Time	19 SEP 2020 11:59

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:09

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 ☒

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:09

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 21:32
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:09

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 ☒

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:09

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 21:41
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:09

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)

118 of 4086

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

120 of 4086

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:09

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 13:34
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:09

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

EAB) (1725)

122 of 4086

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:09

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 12:05
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:09

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)

124 of 4086

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:09

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 13:08
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3172250

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:15:48

Generated On: 09 Jun 2021 15:34:09

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3172250

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:15:48

Generated On: 09 Jun 2021 15:34:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172250

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:15:48

Generated On: 09 Jun 2021 15:34:09

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 2 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3172250

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:15:48

Generated On: 09 Jun 2021 15:34:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172250

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:15:48

Generated On: 09 Jun 2021 15:34:09

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 09 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3172250

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:15:48

Generated On: 09 Jun 2021 15:34:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172250

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:15:48

Generated On: 09 Jun 2021 15:34:09

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

Visit date (dd MMM yyyy)	27 OCT 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT3
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US3172250

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 13:15:48

Generated On: 09 Jun 2021 15:34:09

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 OCT 2020
Time of assessment (00:00-23:59)	08:07 (24 HR)
Vital Signs Date and Time (derived)	27 OCT 2020 08:07
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3172250

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 13:15:48

Generated On: 09 Jun 2021 15:34:09

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.

US3172250

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 13:15:48

Generated On: 09 Jun 2021 15:34:09

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

Collection date (dd MMM yyyy)	27 OCT 2020
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Collection time (00:00-23:59)	08:37 (24 HR)
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Collection date and time (derived)	27 OCT 2020 08:37
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US3172250

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:15:48

Generated On: 09 Jun 2021 15:34:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

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

Date and time of submission

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 NOV 2020 15:25:33
Patient Cloud Open Date & Time	03 NOV 2020 00:01
Patient Cloud Close Date & Time	07 NOV 2020 23:59

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 NOV 2020 09:17:00

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 NOV 2020 22:01:10
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 NOV 2020 19:12:07

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 DEC 2020 22:34:00

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 DEC 2020 08:52:20

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 DEC 2020 12:03:01
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 DEC 2020 13:40:23

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

02 JAN 2021 10:22:56

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

09 JAN 2021 12:28:27

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 JAN 2021 08:34:03
Patient Cloud Open Date & Time	16 JAN 2021 00:01
Patient Cloud Close Date & Time	20 JAN 2021 23:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	23 JAN 2021 18:04:36
Patient Cloud Open Date & Time	23 JAN 2021 00:01
Patient Cloud Close Date & Time	27 JAN 2021 23:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	31 JAN 2021 21:14:18
Patient Cloud Open Date & Time	30 JAN 2021 00:01
Patient Cloud Close Date & Time	03 FEB 2021 23:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 FEB 2021 05:16:27

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

16 FEB 2021 18:15:56

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 FEB 2021 20:43:21
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 FEB 2021 06:03:04

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	False
Chills	False
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	True
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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"/>

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

06 MAR 2021 02:54:19

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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 <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	13 MAR 2021 11:59:46
Patient Cloud Open Date & Time	13 MAR 2021 00:01
Patient Cloud Close Date & Time	17 MAR 2021 23:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 MAR 2021 18:36:30

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 MAR 2021 21:50:48

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 APR 2021 08:41:51

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

11 APR 2021 13:02:01

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

19 APR 2021 10:45:25

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 APR 2021 12:00:28

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAY 2021 00:03:40

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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 ☐

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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 ☐

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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 ☐

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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°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 ☐

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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"/>

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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 ☐

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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 ☐
Yes ☐

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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 ☐

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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 ☐

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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
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Patient Cloud Close Date & Time	18 AUG 2021 23:59
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US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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 ☐

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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°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 ☐

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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 ☐

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

DAY 404

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

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

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

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

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

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

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

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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"/>

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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 ☐

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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 ☐
Yes ☐

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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 ☐

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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 ☐

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

Patient Cloud Open Date & Time	13 NOV 2021 00:01
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Patient Cloud Close Date & Time	17 NOV 2021 23:59
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US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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"/>

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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 ☐
Yes ☐

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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 ☐

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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 ☐

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 JAN 2022 00:01
Patient Cloud Close Date & Time	19 JAN 2022 23:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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°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 ☐

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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°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 ☐

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

DAY 544

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

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

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

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

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

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

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

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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 ☐

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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 ☐

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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°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 ☐

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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 ☐

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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 ☐

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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 ☐

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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 ☐

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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"/>

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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 ☐

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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°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 ☐

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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°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 ☐

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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 ☐

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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 ☐

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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 ☐

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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"/>

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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 ☐

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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"/>

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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°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 ☐

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

DAY 705

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

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

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

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

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

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

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

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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 ☐

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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 ☐

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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"/>

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

Patient Cloud Open Date & Time	20 AUG 2022 00:01
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Patient Cloud Close Date & Time	24 AUG 2022 23:59
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US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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 ☐

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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 ☐

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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 ☐

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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 ☐

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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 ☐

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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 ☐

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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 ☐

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

Patient Cloud Open Date & Time	15 OCT 2022 00:01
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Patient Cloud Close Date & Time	19 OCT 2022 23:59
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US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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"/>

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:34:09

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		13 MAR 2021 12:00:04

US3172250

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:15:48

Generated On: 09 Jun 2021 15:34:09

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3172250

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:15:48

Generated On: 09 Jun 2021 15:34:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172250

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:15:47

Generated On: 09 Jun 2021 15:34:09

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3172250

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:15:47

Generated On: 09 Jun 2021 15:34:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172250

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:15:47

Generated On: 09 Jun 2021 15:34:09

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3172250

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:15:47

Generated On: 09 Jun 2021 15:34:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172250

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:37:26

Generated On: 09 Jun 2021 15:34:09

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3172250

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:37:26

Generated On: 09 Jun 2021 15:34:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172250

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 22 Apr 2021 16:26:39

Generated On: 09 Jun 2021 15:34:09

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

Visit date (dd MMM yyyy)	24 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3172250

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Apr 2021 16:26:39

Generated On: 09 Jun 2021 15:34:09

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 MAR 2021
Time of assessment (00:00-23:59)	10:15 (24 HR)
Vital Signs Date and Time (derived)	24 MAR 2021 10:15
Temperature (xxx.x)	36.5 C
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)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3172250

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Apr 2021 16:26:39

Generated On: 09 Jun 2021 15:34:09

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 MAR 2021

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

US3172250

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Apr 2021 16:26:39

Generated On: 09 Jun 2021 15:34:09

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 24 MAR 2021

Collection time (00:00-23:59) 13:36 (24 HR)

Collection date and time (derived) 24 MAR 2021 13:36

US3172250

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 16:26:39

Generated On: 09 Jun 2021 15:34:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172250

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 16:26:39

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 16:26:39

Generated On: 09 Jun 2021 15:34:09

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3172250

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:34:09

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3172250

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

Form: Visit Date

Data signed: (b) (4) 03 Mar 2021 13:55:57

Generated On: 09 Jun 2021 15:34:09

Was this visit performed? Yes ☒
No ☐

Visit date (dd MMM yyyy) 24 FEB 2021

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

Folder OID UNBLND_DECIDE

US3172250

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

Form: Unblinding

Data signed: (b) (4) 22 Apr 2021 16:26:38

Generated On: 09 Jun 2021 15:34:09

Date of updated informed consent (<i>dd MMM yyyy</i>)	06 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>)	24 FEB 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3172250

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 09 Mar 2021 14:41:57

Generated On: 09 Jun 2021 15:34:09

Height	ND - Not Done
Weight	110.6 kg
BMI (xxx.x)	

US3172250

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 09 Mar 2021 14:41:57

Generated On: 09 Jun 2021 15:34:09

Height	ND - Not Done
Weight	110.6 kg
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)	24 FEB 2021
Time of assessment (00:00-23:59)	12:52 (24 HR)
Vital Signs Date and Time (derived)	24 FEB 2021 12:52
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3172250

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 09 Mar 2021 14:41:57

Generated On: 09 Jun 2021 15:34:09

Height	ND - Not Done
Weight	110.6 kg
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)	24 FEB 2021
Time of assessment (00:00-23:59)	15:52 (24 HR)
Vital Signs Date and Time (derived)	24 FEB 2021 15:52
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3172250

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

Form: Physical Examination

Data signed: (b) (4) 03 Mar 2021 13:55:57

Generated On: 09 Jun 2021 15:34:09

Was the physical examination performed?

Yes ☒
No ☐

Date of examination (dd MMM yyyy)

24 FEB 2021

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

US3172250

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

Form: Exposure

Data signed: (b) (4) 03 Mar 2021 13:55:57

Generated On: 09 Jun 2021 15:34:09

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) 24 FEB 2021

What was the treatment time? (00:00-23:59) 15:22 (24 HR)

Treatment Date and Time (derived) 24 FEB 2021 15:22

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

US3172250

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 03 Mar 2021 13:55:57

Generated On: 09 Jun 2021 15:34:09

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 24 FEB 2021

Collection time (00:00-23:59) 15:04 (24 HR)

Collection date and time (derived) 24 FEB 2021 15:04

US3172250

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 03 Mar 2021 13:55:57

Generated On: 09 Jun 2021 15:34:09

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

Collection date (dd MMM yyyy)	24 FEB 2021
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Collection time (00:00 - 23:59)	15:05
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Collection Date and Time (derived)	24 FEB 2021 15:05
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US3172250

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

Form: Continuing

Data signed: (b) (4) 03 Mar 2021 13:55:57

Generated On: 09 Jun 2021 15:34:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172250

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 16:26:39

Generated On: 09 Jun 2021 15:34:09

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

MISSED

If Contact Not Made, please provide Comments

US3172250

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 16:26:39

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 22 Apr 2021 16:26:38

Generated On: 09 Jun 2021 15:34:09

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

Visit date (dd MMM yyyy)	24 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	OLD29
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US3172250

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Apr 2021 16:26:38

Generated On: 09 Jun 2021 15:34:09

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)	24 MAR 2021
Time of assessment (00:00-23:59)	10:15 (24 HR)
Vital Signs Date and Time (derived)	24 MAR 2021 10:15
Temperature (xxx.x)	36.5 C
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)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3172250

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Apr 2021 16:26:38

Generated On: 09 Jun 2021 15:34:09

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)	24 MAR 2021
Time of assessment (00:00-23:59)	14:30 (24 HR)
Vital Signs Date and Time (derived)	24 MAR 2021 14:30
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3172250

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Apr 2021 16:26:38

Generated On: 09 Jun 2021 15:34:09

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 MAR 2021

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

US3172250

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 22 Apr 2021 16:26:38

Generated On: 09 Jun 2021 15:34:09

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) 24 MAR 2021

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

Treatment Date and Time (derived) 24 MAR 2021 14:00

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

US3172250

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 16:26:38

Generated On: 09 Jun 2021 15:34:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172250

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:09

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3172250

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 17 Feb 2021 13:15:39

Generated On: 09 Jun 2021 15:34:09

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3172250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:09

AEID

Adverse event

ANEMIA

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

16 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

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

Persistent or significant disability or incapacity

False

PRODUCTION RELEASE (v12.003

EAB) (1725)

361 of 4086

US3172250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:09

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input 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)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3172250

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:09

AEID	USA-US118-2020-MRNA-1273-P30 1000010
Adverse event	ACUTE EXACERBATION OF CONGESTION HEART FAILURE
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)	12 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	16 SEP 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)	12 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	16 SEP 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
PRODUCTION RELEASE (v12.003 EAB) (1725)	363 of 4086

US3172250

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:09

ON DAY 27TH VISIT SUBJECT
REPORTED AN A/E: ON
12SEP2020 BILATERAL LOWER
EXTRMITY EDEMA REASON
WHY HE WENT TO BROWARD
HOSPITAL, DENIED ADMISSION.
TODAY SITE RECEIVED
MEDICAL RECORDS THAT
REVEALED SUBJECT
ADMISSION FOR 4 DAYS DUE
TO ACUTE EXACERBATION OF
CONGESTION HEART FAILURE.
A/E WAS UPDATED TO SAE.
RELEVANT LABORATORY AND
DIAGNOSTIC TEST RESULTS
THAT WERE PERFORMED ON
SUBJECT WAS TROPONIN I ON
12SEP2020 AT 18:38 WITH
RESULTS OF 0.03. AT 10:38
SUBJECTS TROPONIN I
RESULTS WAS 0.04. LASTLY
SUBJECTS TROPONIN RESULTS
AT 1:19 REMAINED AT 0.04. ALL
THREE LABS WERE
PERFORMED ON 12SEP2020.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3172250

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:09

AEID	USA-US118-2021-MRNA-1273-P30 1000013
Adverse event	LEFT SCIATIC EXACERBATION
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 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 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 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	03 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

366 of 4086

US3172250

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:09

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 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	

US3172250

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:09

SUBJECT WITH PREVIOUSLY
UNDISCLOSED LEFT SCIATICA
ONGOING SINCE 2018 AS
HISTORICAL CHRONIC LOWER
BACK PAIN BOTH SECONDARY
TO 3 HERNIATED LUMBAR
DISCS. TAKING PRN
OXYCODONE WHEN
EXACERBATION AT THIS TIME
WHEN HE REMAINED
ADMITTED AT HIALEAH
HOSPITAL FOR 4 DAYS BEING
TRANSFERRED TO SAINT
CATHERINE REHABILITATION
CENTER WHERE HE STAYED
FOR 1 WEEK BEING
DISCHARGED WITH A STILL
ONGOING SCIATIC LEFT LEG
PAIN WITH INTENSITY FROM 6
TO 10 WHEN HE WAS
ADMITTED. MEDICAL
RECORDS HAVE BEEN
REQUESTED AND ARE
PENDING TO BE
RECEIVED. NASOPHARYNGEAL
SWAB COVID-19 PCR TEST:
28FEB2021 @18:00 RESULTS:
DETECTED.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3172250

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:09

AEID	USA-US118-2021-MRNA-1273-P30 1000013
Adverse event	CHEST PAIN
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 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	27 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	26 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	03 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

369 of 4086

US3172250

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:09

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT THAT WAS ADMITTED ON THAT DAY COMPLAINT OF CHEST PAIN WITH ASSOCIATED EFFORT DYSPNEA AND CONSISTENT WITH NON ST MYOCARDIAL INFECTION AS DESCRIBED IN RESPECTIVE AE.
Serious Adverse Event Derived (CSA Programming Field Only)	1

PRODUCTION RELEASE (v12.003
EAB) (1725)

370 of 4086

US3172250

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:09

Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3172250

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:09

AEID

Adverse event

ELEVATED LIVER FUNCTION
TEST

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)

01 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

372 of 4086

EAB) (1725)

US3172250

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:09

AEID	USA-US118-2021-MRNA-1273-P30 1000013
Adverse event	NON ST MYOCARDIAL INFARCTION (NSTMI)
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 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	01 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	26 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	03 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
PRODUCTION RELEASE (v12.003 EAB) (1725)	374 of 4086

US3172250

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:09

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT THAT BEING ADMITTED WITH CHEST PAIN HAS TROPONIN I LEVELS OF 0.057 MG/ML ON 26FEB2021 CONSISTENT WITH NSTMI THAT RESOLVED 3 DAYS WITH TROPONIN NORMAL LEVELS OF 0.031 ON 01MAR2021.
Serious Adverse Event Derived (CSA Programming Field Only)	1

PRODUCTION RELEASE (v12.003
EAB) (1725)

375 of 4086

US3172250

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:09

Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3172250

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:34:09

AEID	
Adverse event	ASYMPTOMATIC COVID 19 INFECTION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	28 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	11 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

377 of 4086

US3172250

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:34:09

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 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)	

US3172250

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:34:09

AEID	
Adverse event	UPPER ABDOMINAL ASCITES
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)	12 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	15 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

PRODUCTION RELEASE (v12.003
EAB) (1725)

381 of 4086

US3172250

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:34:09

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 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) _____	

US3172250

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:34:09

AEID

Adverse event

DEGENERATIVE L4-5
POSTERIOR DISC BULGE

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)

13 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

383 of 4086

EAB) (1725)

US3172250

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:34:09

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 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)	

US3172250

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:34:09

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

385 of 4086

US3172250

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:34:09

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 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) _____	

US3172250

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:34:09

AEID	
Adverse event	CHRONIC KIDNEY DISEASE (CKD)
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	13 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

US3172250

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:34:09

AEID	USA-US118-2021-MRNA-1273-P30 1000008
Adverse event	ACUTE EXACERBATION OF CHRONIC CONGESTIVE HEART FAILURE
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)	08 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	16 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	08 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	16 FEB 2021
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

389 of 4086

US3172250

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:34:09

AFTER REVIEW OF MEDICAL RECORDS FROM LARKIN HOSPITAL A NEW TERM FROM SOB SAE WAS UPDATED TO ACUTE EXACERBATION OF CHRONIC CONGESTIVE HEART FAILURE. SUBJECT WITH MANIFESTATIONS OF SHORTNESS OF BREATH, CHEST PAIN, AND ACUTE PULMONARY EDEMA AND BILATERAL LOW EXTREMITIES EDEMA SIGNS AND SYMPTOMS. SUBJECT WAS ADMITTED TO PALMETTO HOSPITAL ON FEBRUARY 8, 2021 UNTIL FEBRUARY 10, 2021. RECORDS WILL BE REQUESTED. TWO DAYS LATER WAS ADMITTED TO LARKIN HOSPITAL AGAIN FOR ONGOING SYMPTOMS. SUBJECT DISCHARGED FROM LARKIN HOSPITAL ON FEBRUARY 16, 2021. MEDICAL HISTORY AND CONCOMITANT MEDICATION LOG WERE UPDATED. COVID-19 PCR TEST WAS PERFORMED 13FEB2021 COLLECTION RESULTS NEGATIVE. TROPONIN I WAS ALSO COLLECTED 13FEB2021. RESULTS 0.03 WITH A REFERENCE RANGE OF 0.06-0.29 NG/ML. ON 13FEB2021 THE FOLLOWING PROCEDURES WERE PERFORMED ON SUBJECT: XR CHEST (1VIEW)

US3172250

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:34:09

IMPRESSION: CARDIOMEGALY.
COMPREHENSIVE 2D DOPPLER
AND ECHOCARDIOGRAM
SHOWED LVEF OF 10-15%.
SUBJECT WAS DISCHARGED ON
16FEB2021 WITH ORDER FROM
HOME HEALTH SERVICE AND
TO CONTINUE UNDER
PRIMARY CARE PHYSICIAN
FOLLOW-UP.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	1

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 17 Feb 2021 13:15:40

Generated On: 09 Jun 2021 15:34:09

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

Yes ☒

No ☐

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

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

394 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	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 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	16 SEP 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"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication FUROSEMIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

396 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) UN AUG 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication POTASSIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication CHRONIC HEART FAILURE

Dose per administration 20

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

If dose unit is Other, specify MEQ

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)

398 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	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 FEB 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) UN MAR 2021		
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"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication ENTRESTO

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 24/26

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)

400 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication AMIODARONE

Prophylaxis Yes ☐
No ☒

Indication PAROXYSMAL ATRIAL
FIBRILLATION

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

402 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication ELIQUIS

Prophylaxis Yes ☐
No ☒

Indication ANTICOAGULANT ATRIAL
FIBRILLATION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

404 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	12 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication BUMETANIDE

Prophylaxis Yes ☐
No ☒

Indication CHRONIC HEART FAILURE
DIURETIC

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

406 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2008	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	12 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication CARVEDILOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 3.125

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

408 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	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 FEB 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	12 FEB 2021	
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"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication CHRONIC LOWER BACK PAIN

Dose per administration 300

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)

410 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	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 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)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication DIABETES TYPE II

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

412 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GASTROESOPHAGEAL REFLUX
DISEASE

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

414 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication CHRONIC LOWER BACK PAIN

Dose per administration 650

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)

416 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	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"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication TRAMADOL

Prophylaxis Yes ☐
No ☒

Indication CHRONIC LOWER BACK PAIN

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 6 HOURS

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

418 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		12 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 19 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication FUROSEMIDE

Prophylaxis Yes ☐
No ☒

Indication DIURETIC

Dose per administration 40/4

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

If dose unit is Other, specify MG/ML

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

420 of 4086

EAB) (1725)

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	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)		12 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 16 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication NA CL 0.9% 10 ML

Prophylaxis Yes ☐
No ☒

Indication FLUSH IV CATHETER

Dose per administration 3

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 8 HOURS

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

PRODUCTION RELEASE (v12.003

422 of 4086

EAB) (1725)

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	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)		12 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication NA CL 0.9% 10 ML

Prophylaxis Yes ☐
No ☒

Indication FLUSH IV CATHETER

Dose per administration 3

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 5 MINUTES

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

424 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	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)		12 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 14 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication LEFT SCIATIC EXACERBATION

Dose per administration 10/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

426 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	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"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication NON ST MYOCARDIA
INFARCTION

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

428 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	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)	26 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	04 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication CORONARY ARTERY DISEASE

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

430 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	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 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		04 MAR 2021
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"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication CLOPIDOGREL

Prophylaxis Yes ☐
No ☒

Indication NON ST MYOCARDIAL
INFARCTION

Dose per administration 75

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

432 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	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)	26 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	04 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication	ENOXAPARIN
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	DEEP VENOUS THROMBOSIS PROPHYLAXIS (DVT)
Dose per administration	110/0.73
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	MG/ML
Frequency	once daily <input type="radio"/> twice daily <input checked="" 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 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 checked="" type="radio"/> Transdermal <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

434 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	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)	26 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		04 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication GLUCAGON

Prophylaxis Yes ☒
No ☐

Indication SEVERE HYPOGLYCEMIA
PROPHYLAXES

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

436 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input checked="" type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	26 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		04 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication ROSUVASTATIN

Prophylaxis Yes ☐
No ☒

Indication CORONARY ARTERY DISEASE
DYSLIPIDEMIA

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

438 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	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)	26 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	04 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication SPIRONOLACTONE

Prophylaxis Yes ☐
No ☒

Indication CHRONIC HEART FAILURE

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

440 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	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 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 25 MAR 2021		
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"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication LEFT SCIATICA

Dose per administration 650

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)

442 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	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 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		04 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication CLONIDINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION EMERGENCY

Dose per administration 0.1

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)

444 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	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 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		04 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication DEXTROSE 10%

Prophylaxis Yes ☒
No ☐

Indication SEVERE HYPOGLYCEMIA
PROPHYLAXIS

Dose per administration 250

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)

446 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	26 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		04 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication GLUCOSE (D50 SYRINGE)

Prophylaxis Yes ☒
No ☐

Indication SEVERE HYPOGLYCEMIA
PROPHYLAXIS

Dose per administration 159/50

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

448 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	26 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		04 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication HYDROMORPHONE

Prophylaxis Yes ☐
No ☒

Indication CHEST PAIN / SCIATICA

Dose per administration 0.5/0.5

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

If dose unit is Other, specify MG/ML

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)

450 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	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 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		04 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"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication INSULIN REGULAR

Prophylaxis Yes ☐
No ☒

Indication DIABETES MELLITUS

Dose per administration

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)

452 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	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 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		04 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication KETOROLAC

Prophylaxis Yes ☐
No ☒

Indication SCIATICA

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 ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

454 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	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 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		04 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication LORAZEPAM

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

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)

456 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	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 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		04 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication NITROGLYCERIN

Prophylaxis Yes ☐
No ☒

Indication CHEST PAIN

Dose per administration 0.4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

458 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	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 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		04 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication ONDANSETRON

Prophylaxis Yes ☒
No ☐

Indication EMESIS PROPHYLAXIS

Dose per administration 4/2

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

If dose unit is Other, specify MG/ML

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)

460 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	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 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		04 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"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication DOCUSATE

Prophylaxis Yes ☒
No ☐

Indication CONSTIPATION PROPHYLAXIS

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

462 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	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 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		04 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication FERROUS SULPHATE

Prophylaxis Yes ☐
No ☒

Indication ANEMIA

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

464 of 4086

EAB) (1725)

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	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)	27 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication BUMETADINE

Prophylaxis Yes ☐
No ☒

Indication CHRONIC HEART FAILURE
EXACERBATION

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

466 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	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)	13 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication BUMETANIDE

Prophylaxis Yes ☐
No ☒

Indication CHRONIC HEART FAILURE
EXACERBATION

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

468 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	13 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	16 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication CARVEDILOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

470 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	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)	13 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 13 FEB 2021		
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"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication CARVEDILOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 6.25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

472 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	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)	13 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 13 FEB 2021		
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"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication CARVEDILOL

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

474 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	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)	13 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy) 16 FEB 2021		
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"/>	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication CARVEDILOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 3.125

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

476 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	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 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication ELIQUIS

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 2.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

478 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	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)	13 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy) 16 FEB 2021		
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"/>	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication HEPARIN SODIUMIN D 5 W

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

480 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	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)		13 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 13 FEB 2021		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication HEPARIN SODIUM IN D 5 W

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 25000

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)

482 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	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)	13 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy) 13 FEB 2021		
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input type="radio"/>	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication GLUCAGON

Prophylaxis Yes ☐
No ☒

Indication DIABETES TYPE II

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)

484 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	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)		13 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication INSULIN REGULAR HUMAN

Prophylaxis Yes ☐
No ☒

Indication DIABETES TYPE II

Dose per administration

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

BEFORE MEALS AND BEDTIME

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

PRODUCTION RELEASE (v12.003

486 of 4086

EAB) (1725)

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 16 FEB 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication SODIUM CHLORIDE 0.9

Prophylaxis Yes ☐
No ☒

Indication FLUSH IV CATHETER

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

EVERY 8 HOURS

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

488 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	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)	13 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		16 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIAC PROPHYLAXIS

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

490 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 13 FEB 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIAC PROPHYLAXIS

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

492 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	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)	14 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication PLAVIX

Prophylaxis Yes ☐
No ☒

Indication ACUTE CORONARY SYNDROME

Dose per administration 75

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

494 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	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)	13 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy) 16 FEB 2021		
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"/>	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication	DEXTROSE
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	SEVERE HYPOGLYCEMIA PROPHYLAXIS
Dose per administration	50
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input checked="" type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
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 checked="" type="radio"/> Transdermal <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

496 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	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)	13 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		
		16 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication POTASSIUM CHLORIDE

Prophylaxis Yes ☒
No ☐

Indication HYPOPOTASSEMIA
PROPHYLAXIS

Dose per administration 20

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

If dose unit is Other, specify MEQ

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)

498 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	13 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication INSULIN LISPRO HUMAN

Prophylaxis Yes ☐
No ☒

Indication DIABETES TYPE II

Dose per administration 9

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

If dose unit is Other, specify UNITS

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

500 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	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)	13 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 16 FEB 2021		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication NITROGLYCERIN

Prophylaxis Yes ☐
No ☒

Indication CHEST PAIN

Dose per administration 0.4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

502 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	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	TRANSDERMAL PATCH	
Start date (dd MMM yyyy)	13 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	16 FEB 2021	
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"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication TRAMADOL

Prophylaxis Yes ☐
No ☒

Indication LEFT SCIATIC PAIN

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 6 HOURS

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

504 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	13 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication ENOXAPARIN SODIUM

Prophylaxis Yes ☒
No ☐

Indication HEART ATTACK PROPHYLAXIS

Dose per administration 0.4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

506 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	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)	13 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication MORPHINE

Prophylaxis Yes ☐
No ☒

Indication LEFT SCIATIC PAIN

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

EVERY 4 HOURS / PRN

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

508 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	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)	13 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication INSULIN GLARGINE

Prophylaxis Yes ☐
No ☒

Indication DIABETES TYPE II

Dose per administration 28

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 AT BEDTIME

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

510 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	13 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication SPIRONOLACTONE

Prophylaxis Yes ☐
No ☒

Indication CHRONIC HEART FAILURE
EXACERBATION

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

512 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	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)		13 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication ATORVASTATINAL

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

AT BEDTIME

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

514 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication BACLOFEN

Prophylaxis Yes ☐
No ☒

Indication LEFT SCIATIC PAIN

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

516 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	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 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"/>

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

Name of Medication DICLOFENAC

Prophylaxis Yes ☐
No ☒

Indication LEFT SCIATIC PAIN

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

518 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Data signed: (b) (4) 28 Apr 2021 07:34:06

Generated On: 09 Jun 2021 15:34:09

	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"/>

US3172250

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 17 Feb 2021 13:15:47

Generated On: 09 Jun 2021 15:34:09

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3172250

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 17 Feb 2021 13:15:47

Generated On: 09 Jun 2021 15:34:09

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
12 SEP 2020	X-RAY - RA CHES	Adverse Event	
12 SEP 2020	CT ANGIO PULMONARY ARTERIES	Adverse Event	
12 SEP 2020	EKG	Adverse Event	
13 SEP 2020	X-RAY - RA CHEST	Adverse Event	
13 SEP 2020	CT LUMBAR SPINE	Adverse Event	
15 SEP 2020	US GUIDANCE PARACENTESIS	Adverse Event	

US3172250

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:34:09

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

US3172250

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:34:09

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 ☐

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

SAEID	USA-US118-2020-MRNA-1273-P301000010
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	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:34:09

SAEID	USA-US118-2020-MRNA-1273-P301000010
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	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	13/NOV/2020 12:58
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:34:09

SAEID	USA-US118-2020-MRNA-1273-P301000010
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	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	25/NOV/2020 11:00
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

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:34:09

SAEID	USA-US118-2020-MRNA-1273-P301000010
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	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	02/DEC/2020 13:25
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:34:09

SAEID	USA-US118-2020-MRNA-1273-P301000010
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	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	19/FEB/2021 09:39
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

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:34:09

SAEID	USA-US118-2020-MRNA-1273-P301000010
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	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	26/APR/2021 14:12
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

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:34:09

SAEID	USA-US118-2020-MRNA-1273-P301000010
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	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	03/MAY/2021 11:52
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

SAEID	USA-US118-2021-MRNA-1273-P301000008
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	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:34:09

SAEID	USA-US118-2021-MRNA-1273-P301000008
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	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	19/FEB/2021 21:21
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

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:34:09

SAEID	USA-US118-2021-MRNA-1273-P301000008
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	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	03/MAR/2021 11:02
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:34:09

SAEID	USA-US118-2021-MRNA-1273-P301000008
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	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	19/APR/2021 08:08
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

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:34:09

SAEID	USA-US118-2021-MRNA-1273-P301000008
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	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	26/APR/2021 13:20
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

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:34:09

SAEID	USA-US118-2021-MRNA-1273-P301000008
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	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	03/MAY/2021 12:07
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

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 07:34:09

Generated On: 09 Jun 2021 15:34:09

SAEID	USA-US118-2021-MRNA-1273-P301000013
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	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 07:34:09

Generated On: 09 Jun 2021 15:34:09

SAEID	USA-US118-2021-MRNA-1273-P301000013
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	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	25/MAR/2021 09:14
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

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 07:34:09

Generated On: 09 Jun 2021 15:34:09

SAEID	USA-US118-2021-MRNA-1273-P301000013
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	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	06/APR/2021 14:11
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

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 07:34:09

Generated On: 09 Jun 2021 15:34:09

SAEID	USA-US118-2021-MRNA-1273-P301000013
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	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	14/APR/2021 13:55
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 07:34:09

Generated On: 09 Jun 2021 15:34:09

SAEID	USA-US118-2021-MRNA-1273-P301000013
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	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	15/APR/2021 10:25
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form (5)

Data signed: (b) (4) 28 Apr 2021 07:34:09

Generated On: 09 Jun 2021 15:34:09

SAEID	USA-US118-2021-MRNA-1273-P301000013
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	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	26/APR/2021 11:13
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

US3172250 (Prod: Suncoast Research Group LLC - ERN-PPDS)

US3172250

Form: Participant Creation

Generated On: 09 Jun 2021 15:34:09

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'US3172250'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	20 Aug 2020 18:20:13

US3172250

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:34:09

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:46:15

US3172250

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '20 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	20 Aug 2020 18:20:14

US3172250

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Clinic (Clinic)'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:46:15

US3172250

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:34:09

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered 'SCRN'	System	20 Aug 2020 19:46:15

US3172250

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:34:09

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered (b) (6) 1961'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	20 Aug 2020 18:20:15

US3172250

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:34:09

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '59'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:47:25

US3172250

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:34:09

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered 'YEARS'	System	20 Aug 2020 19:47:25

US3172250

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:34:09

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered '59'	System	20 Aug 2020 19:43:41

US3172250

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:34:09

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Male (M)'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:47:25

US3172250

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:34:09

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:47:25

US3172250

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:34:09

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'I'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:47:25

US3172250

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:34:09

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '0'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:47:25

US3172250

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:34:09

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '0'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:47:25

US3172250

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:34:09

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '0'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:47:25

US3172250

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:34:09

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '0'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:47:25

US3172250

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:34:09

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '0'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:47:25

US3172250

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:34:09

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:47:25

US3172250

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:34:09

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '0'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:47:25

US3172250

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:34:09

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '0'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:47:25

US3172250

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:34:09

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '20 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:43:41

US3172250

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered 'Aug 2020'	System	20 Aug 2020 19:43:41

US3172250

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered '2020'	System	20 Aug 2020 19:43:41

US3172250

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:34:09

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Amendment 1 (1)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 19:07:03
User entered 'Amendment 2 (2)'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:43:41

US3172250

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:43:41

US3172250

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:43:41

US3172250

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:34:09

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:43:41

US3172250

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:34:09

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:43:41

US3172250

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:34:09

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	20 Aug 2020 18:20:14

US3172250

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:34:09

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered 'I'	System	20 Aug 2020 19:43:46

US3172250

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:43:46

US3172250

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:34:09

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:50:34

US3172250

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:34:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Sleep apnea - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:52:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:52:19
Data point term sent to Coder	System	20 Aug 2020 19:51:39
User entered 'SLEEP APNEA'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:50:55

US3172250

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'UN UNK 2017'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:50:55

US3172250

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '0'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:50:55

US3172250

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:34:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:50:55

US3172250

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:50:55

US3172250

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:34:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '0'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:50:55

US3172250

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered 'Jan 2017'	System	20 Aug 2020 19:50:55

US3172250

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered '2017'	System	20 Aug 2020 19:50:55

US3172250

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered empty.	System	20 Aug 2020 19:50:55

US3172250

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered empty.	System	20 Aug 2020 19:50:55

US3172250

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:34:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Jan 2021 18:35:04
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Jan 2021 18:35:04
Data point term sent to Coder	System	22 Jan 2021 22:22:28
Coding entries removed.	Mariete Rendon (b) (4) (b) (4)	22 Jan 2021 22:21:32
User entered 'HYPERTENSION Mild' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	22 Jan 2021 22:21:32
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:52:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:52:19
Data point term sent to Coder	System	20 Aug 2020 19:51:39
User entered 'HYPERTENSION'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:51:16

US3172250

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'UN UNK 1986'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:51:16

US3172250

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '0'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:51:16

US3172250

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:34:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:51:16

US3172250

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:51:16

US3172250

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:34:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '0'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:51:16

US3172250

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered 'Jan 1986'	System	20 Aug 2020 19:51:16

US3172250

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered '1986'	System	20 Aug 2020 19:51:16

US3172250

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered empty.	System	20 Aug 2020 19:51:16

US3172250

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered empty.	System	20 Aug 2020 19:51:16

US3172250

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:34:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholelithiasis, LLT: Gallstones - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:52:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:52:18
Data point term sent to Coder	System	20 Aug 2020 19:51:40
User entered 'GALLSTONES'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:51:40

US3172250

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'UN UNK 2016'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:51:40

US3172250

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '0'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:51:40

US3172250

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:34:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:51:40

US3172250

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'UN UNK 2016'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:51:40

US3172250

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:34:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '0'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:51:40

US3172250

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered 'Jan 2016'	System	20 Aug 2020 19:51:40

US3172250

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered '2016'	System	20 Aug 2020 19:51:40

US3172250

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered 'Jan 2016'	System	20 Aug 2020 19:51:40

US3172250

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered '2016'	System	20 Aug 2020 19:51:40

US3172250

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:34:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:53:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:53:22
Data point term sent to Coder	System	20 Aug 2020 19:52:42
User entered 'SEVERE OBESITY'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:51:54

US3172250

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'UN UNK 2015'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:51:54

US3172250

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '0'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:51:54

US3172250

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:34:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:51:54

US3172250

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:51:54

US3172250

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:34:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '0'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:51:54

US3172250

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered 'Jan 2015'	System	20 Aug 2020 19:51:54

US3172250

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered '2015'	System	20 Aug 2020 19:51:54

US3172250

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered empty.	System	20 Aug 2020 19:51:54

US3172250

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered empty.	System	20 Aug 2020 19:51:54

US3172250

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:34:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
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) (b) (4)	20 Aug 2020 19:53:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:53:22
Data point term sent to Coder	System	20 Aug 2020 19:52:47
User entered 'ERECTILE DYSFUNCTION'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:52:18

US3172250

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'UN UNK 2015'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:52:18

US3172250

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '0'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:52:18

US3172250

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:34:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:52:18

US3172250

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'UN UNK 2015'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:52:18

US3172250

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:34:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '0'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:52:18

US3172250

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered 'Jan 2015'	System	20 Aug 2020 19:52:18

US3172250

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered '2015'	System	20 Aug 2020 19:52:18

US3172250

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered 'Jan 2015'	System	20 Aug 2020 19:52:18

US3172250

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered '2015'	System	20 Aug 2020 19:52:18

US3172250

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:34:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Back pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:53:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:53:23
Data point term sent to Coder	System	20 Aug 2020 19:52:47
User entered 'BACK PAIN'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:52:38

US3172250

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'UN UNK 2018'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:52:38

US3172250

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '0'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:52:38

US3172250

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:34:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:52:38

US3172250

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:52:38

US3172250

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:34:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '0'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:52:38

US3172250

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered 'Jan 2018'	System	20 Aug 2020 19:52:38

US3172250

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered '2018'	System	20 Aug 2020 19:52:38

US3172250

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered empty.	System	20 Aug 2020 19:52:38

US3172250

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered empty.	System	20 Aug 2020 19:52:38

US3172250

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:34:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Musculoskeletal and connective tissue disorders congenital, HLT: Musculoskeletal and connective tissue disorders of limbs congenital, PT: Ectrodactyly, LLT: Ectrodactyly - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Apr 2021 09:16:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Apr 2021 09:16:39
Data point term sent to Coder	System	23 Apr 2021 17:51:11
Coding entries removed.	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 17:51:01
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 17:51:01
User entered 'congenital ECTRODOCTYLIA' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 17:51:01
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Musculoskeletal and connective tissue disorders congenital, HLT: Musculoskeletal and connective tissue disorders of limbs congenital, PT: Ectrodactyly, LLT: Ectrodactyly - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 15:03:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 15:03:31
Data point term sent to Coder	System	20 Aug 2020 19:53:48
User entered 'ECTRODOCTYLIA'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:53:14

US3172250

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:34:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 18:07:36
User entered (b) (6) 1961' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 18:07:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	26 Aug 2020 18:53:45
User entered '20 Aug 2020' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	26 Aug 2020 18:53:45
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	20 Aug 2020 19:53:14
User entered empty.	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:53:14

US3172250

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '0'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:53:14

US3172250

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:34:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:53:14

US3172250

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:53:14

US3172250

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:34:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '0'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:53:14

US3172250

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered (b) (6) 1961'	System	23 Apr 2021 18:07:36
User entered 'Aug 2020'	System	26 Aug 2020 18:53:45
User entered empty.	System	20 Aug 2020 19:53:14

US3172250

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered '1961'	System	23 Apr 2021 18:07:36
User entered '2020'	System	26 Aug 2020 18:53:45
User entered empty.	System	20 Aug 2020 19:53:14

US3172250

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered empty.	System	20 Aug 2020 19:53:14

US3172250

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered empty.	System	20 Aug 2020 19:53:14

US3172250

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:34:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:55:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:55:22
Data point term sent to Coder	System	20 Aug 2020 19:54:50
User entered 'LAPAROSCOPIC CHOLECYSTECTOMY'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:54:09

US3172250

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'UN UNK 2016'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:54:09

US3172250

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '0'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:54:09

US3172250

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:34:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:54:09

US3172250

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'UN UNK 2016'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:54:09

US3172250

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:34:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '0'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:54:09

US3172250

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered 'Jan 2016'	System	20 Aug 2020 19:54:09

US3172250

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered '2016'	System	20 Aug 2020 19:54:09

US3172250

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered 'Jan 2016'	System	20 Aug 2020 19:54:09

US3172250

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered '2016'	System	20 Aug 2020 19:54:09

US3172250

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:34:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Penile therapeutic procedures, PT: Penile prosthesis insertion, LLT: Penile implant - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:55:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 19:55:22
Data point term sent to Coder	System	20 Aug 2020 19:54:50
User entered 'PENILE IMPLANT'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:54:29

US3172250

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'UN UNK 2017'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:54:29

US3172250

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '0'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:54:29

US3172250

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:34:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:54:29

US3172250

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'UN UNK 2017'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:54:29

US3172250

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:34:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '0'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:54:29

US3172250

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered 'Jan 2017'	System	20 Aug 2020 19:54:29

US3172250

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered '2017'	System	20 Aug 2020 19:54:29

US3172250

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered 'Jan 2017'	System	20 Aug 2020 19:54:29

US3172250

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered '2017'	System	20 Aug 2020 19:54:29

US3172250

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:34:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Heart attack - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 19:41:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 19:41:56
Data point term sent to Coder	System	24 Nov 2020 19:40:28
User entered 'heart attack'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:40:08

US3172250

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'un UNK 2017'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:40:08

US3172250

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:40:08

US3172250

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:34:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:40:08

US3172250

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'un UNK 2017'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:40:08

US3172250

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:34:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:40:08

US3172250

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered 'Jan 2017'	System	24 Nov 2020 19:40:08

US3172250

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered '2017'	System	24 Nov 2020 19:40:08

US3172250

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered 'Jan 2017'	System	24 Nov 2020 19:40:08

US3172250

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered '2017'	System	24 Nov 2020 19:40:08

US3172250

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:34:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Cardiac device therapeutic procedures, PT: Implantable defibrillator insertion, LLT: Implantable cardioverter defibrillator insertion - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 06:52:09
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 06:52:09
Data point term sent to Coder	System	24 Nov 2020 19:47:37
User entered 'post automated implantable cardioverter defibrillator congestive heart failure'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:47:18

US3172250

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'un UNK 2008'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:47:18

US3172250

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:47:18

US3172250

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:34:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:47:18

US3172250

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:47:18

US3172250

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:34:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:47:18

US3172250

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered 'Jan 2008'	System	24 Nov 2020 19:47:18

US3172250

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered '2008'	System	24 Nov 2020 19:47:18

US3172250

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered empty.	System	24 Nov 2020 19:47:18

US3172250

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered empty.	System	24 Nov 2020 19:47:18

US3172250

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:34:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Cardiac device therapeutic procedures, PT: Cardiac resynchronisation therapy, LLT: Biventricular pacemaker insertion - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 06:52:09
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 06:52:09
Data point term sent to Coder	System	24 Nov 2020 19:48:37
User entered 'BIVENTRICULOR DUAL CHAMBER' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:48:29
User entered 'BIVENTRICULOR'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:48:03

US3172250

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 17:36:13
User entered '04 Dec 2016' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 17:36:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '04 Dec 2017'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:48:03

US3172250

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:48:03

US3172250

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:34:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:48:03

US3172250

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:48:03

US3172250

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:34:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:48:03

US3172250

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered 'Dec 2016'	System	23 Apr 2021 17:36:13
User entered 'Dec 2017'	System	24 Nov 2020 19:48:03

US3172250

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered '2016'	System	23 Apr 2021 17:36:13
User entered '2017'	System	24 Nov 2020 19:48:03

US3172250

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered empty.	System	24 Nov 2020 19:48:03

US3172250

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered empty.	System	24 Nov 2020 19:48:03

US3172250

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:34:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
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) (b) (4)	24 Nov 2020 19:51:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 19:51:03
Data point term sent to Coder	System	24 Nov 2020 19:49:42
User entered 'HYPERLIPIDEMIA'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:49:24

US3172250

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'UN UNK 2017'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:49:24

US3172250

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:49:24

US3172250

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:34:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:49:24

US3172250

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:49:24

US3172250

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:34:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:49:24

US3172250

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered 'Jan 2017'	System	24 Nov 2020 19:49:24

US3172250

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered '2017'	System	24 Nov 2020 19:49:24

US3172250

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered empty.	System	24 Nov 2020 19:49:24

US3172250

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered empty.	System	24 Nov 2020 19:49:24

US3172250

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:34:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Paroxysmal atrial fibrillation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 19:53:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 19:53:07
Data point term sent to Coder	System	24 Nov 2020 19:51:45
User entered 'paroxysmal atrial fibrillation'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:51:26

US3172250

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'un UNK 2008'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:51:26

US3172250

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:51:26

US3172250

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:34:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:51:26

US3172250

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:51:26

US3172250

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:34:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:51:26

US3172250

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered 'Jan 2008'	System	24 Nov 2020 19:51:26

US3172250

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered '2008'	System	24 Nov 2020 19:51:26

US3172250

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered empty.	System	24 Nov 2020 19:51:26

US3172250

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered empty.	System	24 Nov 2020 19:51:26

US3172250

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:34:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User coded data point as SOC: Cardiac disorders, HLGT: Myocardial disorders, HLT: Cardiomyopathies, PT: Ischaemic cardiomyopathy, LLT: Ischemic cardiomyopathy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 19:53:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 19:53:56
Data point term sent to Coder	System	24 Nov 2020 19:52:47
User entered 'ischemic cardiomyopathy'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:52:38

US3172250

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'un UNK 2008'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:52:38

US3172250

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:52:38

US3172250

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:34:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:52:38

US3172250

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:52:38

US3172250

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:34:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:52:38

US3172250

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered 'Jan 2008'	System	24 Nov 2020 19:52:38

US3172250

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered '2008'	System	24 Nov 2020 19:52:38

US3172250

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered empty.	System	24 Nov 2020 19:52:38

US3172250

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered empty.	System	24 Nov 2020 19:52:38

US3172250

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:34:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
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) (b) (4)	24 Nov 2020 19:56:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 19:56:01
Data point term sent to Coder	System	24 Nov 2020 19:54:48
User entered 'Gastroesophageal reflux disease'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:54:15

US3172250

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	24 Nov 2020 19:54:33
User entered 'un UNK 2015' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:54:33
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	24 Nov 2020 19:54:15
User entered ' UNK 2015' (non-conformant).	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:54:15

US3172250

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:54:15

US3172250

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:34:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:54:15

US3172250

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:54:15

US3172250

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:34:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:54:15

US3172250

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered 'Jan 2015'	System	24 Nov 2020 19:54:33
User entered empty.	System	24 Nov 2020 19:54:15

US3172250

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered '2015'	System	24 Nov 2020 19:54:33
User entered empty.	System	24 Nov 2020 19:54:15

US3172250

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered empty.	System	24 Nov 2020 19:54:15

US3172250

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered empty.	System	24 Nov 2020 19:54:15

US3172250

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:34:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 19:56:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 19:56:58
Data point term sent to Coder	System	24 Nov 2020 19:55:49
User entered 'diabetes type ii'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:55:35

US3172250

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'un UNK 2015'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:55:35

US3172250

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:55:35

US3172250

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:34:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:55:35

US3172250

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:34:09

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:55:35

US3172250

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:34:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:55:35

US3172250

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered 'Jan 2015'	System	24 Nov 2020 19:55:35

US3172250

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered '2015'	System	24 Nov 2020 19:55:35

US3172250

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered empty.	System	24 Nov 2020 19:55:35

US3172250

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered empty.	System	24 Nov 2020 19:55:35

US3172250

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:34:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebrovascular accident, LLT: Cerebrovascular accident - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 20:01:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 20:01:01
Data point term sent to Coder	System	24 Nov 2020 20:00:00
User entered 'cerebrovascular accident'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:59:07

US3172250

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '04 Jul 2020'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:59:07

US3172250

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:59:07

US3172250

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:34:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:59:07

US3172250

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '04 Jul 2020'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:59:07

US3172250

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:34:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 19:59:07

US3172250

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered 'Jul 2020'	System	24 Nov 2020 19:59:07

US3172250

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered '2020'	System	24 Nov 2020 19:59:07

US3172250

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered 'Jul 2020'	System	24 Nov 2020 19:59:07

US3172250

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered '2020'	System	24 Nov 2020 19:59:07

US3172250

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:34:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User coded data point as SOC: Nervous system disorders, HLGT: Spinal cord and nerve root disorders, HLT: Lumbar spinal cord and nerve root disorders, PT: Sciatica, LLT: Sciatica - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 20:01:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 20:01:56
Data point term sent to Coder	System	24 Nov 2020 20:01:01
User entered 'left side sciatica'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:00:55

US3172250

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'un UNK 2015'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:00:55

US3172250

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:00:55

US3172250

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:34:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:00:55

US3172250

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'un UNK 2015'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:00:55

US3172250

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:34:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '0'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:00:55

US3172250

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered 'Jan 2015'	System	24 Nov 2020 20:00:55

US3172250

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered '2015'	System	24 Nov 2020 20:00:55

US3172250

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered 'Jan 2015'	System	24 Nov 2020 20:00:55

US3172250

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered '2015'	System	24 Nov 2020 20:00:55

US3172250

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:34:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Chronic polyneuropathies, PT: Diabetic neuropathy, LLT: Diabetic peripheral neuropathy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Mar 2021 07:08:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Mar 2021 07:08:47
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:55:57
Data point term sent to Coder	System	02 Mar 2021 20:06:02
User entered 'SENSORIAL Diabetic Peripheral Neuropathy'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:05:04

US3172250

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:55:57
User entered 'UN UNK 2018'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:05:04

US3172250

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:55:57
User entered '0'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:05:04

US3172250

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:34:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:55:57
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:05:04

US3172250

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:55:57
User entered empty.	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:05:04

US3172250

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:34:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:55:57
User entered '0'	Jessie Downs (b) (4) (b) (4)	02 Mar 2021 20:05:04

US3172250

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered 'Jan 2018'	System	02 Mar 2021 20:05:04

US3172250

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered '2018'	System	02 Mar 2021 20:05:04

US3172250

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered empty.	System	02 Mar 2021 20:05:04

US3172250

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered empty.	System	02 Mar 2021 20:05:04

US3172250

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:34:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Ischaemic stroke, LLT: Ischemic stroke - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Apr 2021 12:45:12
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Apr 2021 12:45:12
Data point term sent to Coder	System	16 Apr 2021 20:00:11
User entered 'stroke vs. transient ischemic attacks'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 20:00:06

US3172250

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 17:38:40
User entered 'UN Apr 2020' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 17:38:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered 'un UNK 2020'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 20:00:06

US3172250

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered '0'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 20:00:06

US3172250

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:34:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 20:00:06

US3172250

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:34:09

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 17:38:40
User entered 'UN Apr 2020' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 17:38:40
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered 'un UNK 2020'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 20:00:06

US3172250

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:34:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered '0'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 20:00:06

US3172250

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered 'Apr 2020'	System	23 Apr 2021 17:38:40
User entered 'Jan 2020'	System	16 Apr 2021 20:00:06

US3172250

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered '2020'	System	16 Apr 2021 20:00:06

US3172250

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered 'Apr 2020'	System	23 Apr 2021 17:38:40
User entered 'Jan 2020'	System	16 Apr 2021 20:00:06

US3172250

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered '2020'	System	16 Apr 2021 20:00:06

US3172250

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:34:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Infections NEC, PT: Device related infection, LLT: Implant infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Apr 2021 13:34:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Apr 2021 13:34:01
Data point term sent to Coder	System	16 Apr 2021 20:02:22
User entered 'penile implant infection and removal of prosthesis'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 20:01:44

US3172250

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered '19 May 2020'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 20:01:44

US3172250

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered '0'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 20:01:44

US3172250

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:34:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 20:01:44

US3172250

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:34:09

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered '30 Jun 2020'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 20:01:44

US3172250

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:34:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered '0'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 20:01:44

US3172250

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered 'May 2020'	System	16 Apr 2021 20:01:44

US3172250

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered '2020'	System	16 Apr 2021 20:01:44

US3172250

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered 'Jun 2020'	System	16 Apr 2021 20:01:44

US3172250

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered '2020'	System	16 Apr 2021 20:01:44

US3172250

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 15:34:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User coded data point as SOC: Investigations, HLG: Cardiac and vascular investigations (excl enzyme tests), HLT: Cardiac imaging procedures, PT: Catheterisation cardiac, LLT: Cardiac catheterization - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Apr 2021 08:56:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Apr 2021 08:56:38
Data point term sent to Coder	System	23 Apr 2021 17:41:03
User entered 'cardiac catheter'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 17:40:42

US3172250

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'un UNK 2012'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 17:40:42

US3172250

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered '0'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 17:40:42

US3172250

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 15:34:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Apr 2021 17:40:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Apr 2021 17:40:47
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 17:40:47
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Apr 2021 17:40:42
User entered empty.	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 17:40:42

US3172250

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'un UNK 2012'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 17:40:42

US3172250

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 15:34:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered '0'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 17:40:42

US3172250

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered 'Jan 2012'	System	23 Apr 2021 17:40:42

US3172250

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered '2012'	System	23 Apr 2021 17:40:42

US3172250

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered 'Jan 2012'	System	23 Apr 2021 17:40:42

US3172250

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered '2012'	System	23 Apr 2021 17:40:42

US3172250

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 15:34:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User coded data point as SOC: Investigations, HLG: Cardiac and vascular investigations (excl enzyme tests), HLT: Cardiac imaging procedures, PT: Catheterisation cardiac, LLT: Cardiac catheterization - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Apr 2021 08:56:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Apr 2021 08:56:38
Data point term sent to Coder	System	23 Apr 2021 17:42:04
User entered 'cardiac catheter'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 17:41:05

US3172250

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'un UNK 2016'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 17:41:05

US3172250

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered '0'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 17:41:05

US3172250

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 15:34:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 17:41:05

US3172250

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'un UNK 2016'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 17:41:05

US3172250

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 15:34:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered '0'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 17:41:05

US3172250

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered 'Jan 2016'	System	23 Apr 2021 17:41:05

US3172250

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered '2016'	System	23 Apr 2021 17:41:05

US3172250

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered 'Jan 2016'	System	23 Apr 2021 17:41:05

US3172250

Folder: Screening

Form: Medical History (24)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered '2016'	System	23 Apr 2021 17:41:05

US3172250

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 15:34:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User coded data point as SOC: Investigations, HLG: Cardiac and vascular investigations (excl enzyme tests), HLT: Cardiac imaging procedures, PT: Catheterisation cardiac, LLT: Cardiac catheterization - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Apr 2021 08:56:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Apr 2021 08:56:38
Data point term sent to Coder	System	23 Apr 2021 17:42:04
User entered 'cardiac catheter'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 17:41:23

US3172250

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'un UNK 2018'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 17:41:23

US3172250

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered '0'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 17:41:23

US3172250

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 15:34:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 17:41:23

US3172250

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'un UNK 2018'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 17:41:23

US3172250

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 15:34:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered '0'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 17:41:23

US3172250

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered 'Jan 2018'	System	23 Apr 2021 17:41:23

US3172250

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered '2018'	System	23 Apr 2021 17:41:23

US3172250

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered 'Jan 2018'	System	23 Apr 2021 17:41:23

US3172250

Folder: Screening

Form: Medical History (25)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered '2018'	System	23 Apr 2021 17:41:23

US3172250

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 15:34:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Cardiac device therapeutic procedures, PT: Implantable defibrillator insertion, LLT: Implantable defibrillator insertion - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Apr 2021 17:44:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Apr 2021 17:44:05
Data point term sent to Coder	System	23 Apr 2021 17:43:05
User entered 'defibrillator'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 17:42:49

US3172250

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered '04 Dec 2008'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 17:42:49

US3172250

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered '0'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 17:42:49

US3172250

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 15:34:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 17:42:49

US3172250

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered '04 Dec 2016'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 17:42:49

US3172250

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 15:34:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered '0'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 17:42:49

US3172250

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered 'Dec 2008'	System	23 Apr 2021 17:42:49

US3172250

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered '2008'	System	23 Apr 2021 17:42:49

US3172250

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered 'Dec 2016'	System	23 Apr 2021 17:42:49

US3172250

Folder: Screening

Form: Medical History (26)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered '2016'	System	23 Apr 2021 17:42:49

US3172250

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 15:34:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User coded data point as SOC: Nervous system disorders, HLGT: Spinal cord and nerve root disorders, HLT: Lumbar spinal cord and nerve root disorders, PT: Sciatica, LLT: Sciatica - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Apr 2021 17:45:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Apr 2021 17:45:49
Data point term sent to Coder	System	23 Apr 2021 17:45:06
User entered 'left sciatica'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 17:44:08

US3172250

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'un UNK 2015'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 17:44:08

US3172250

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered '0'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 17:44:08

US3172250

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 15:34:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 17:44:08

US3172250

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 17:44:08

US3172250

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 15:34:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered '0'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 17:44:08

US3172250

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered 'Jan 2015'	System	23 Apr 2021 17:44:08

US3172250

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered '2015'	System	23 Apr 2021 17:44:08

US3172250

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered empty.	System	23 Apr 2021 17:44:08

US3172250

Folder: Screening

Form: Medical History (27)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered empty.	System	23 Apr 2021 17:44:08

US3172250

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:48:01

US3172250

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '20 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:48:01

US3172250

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '11:43'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:48:01

US3172250

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered '20 Aug 2020 11:43'	System	20 Aug 2020 19:48:01

US3172250

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '163.0' cm	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:48:01
DataPoint set to visible.	System	20 Aug 2020 19:43:46

US3172250

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '117.0' kg	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:48:01
DataPoint set to visible.	System	20 Aug 2020 19:43:46

US3172250

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
Amendment Manager: User entered '44.03628'	System	17 Sep 2020 00:16:38
User entered '44.0'	System	20 Aug 2020 19:48:01
DataPoint set to visible.	System	20 Aug 2020 19:43:46

US3172250

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered 'kg/m2'	System	20 Aug 2020 19:48:01
DataPoint set to visible.	System	20 Aug 2020 19:43:46

US3172250

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:48:01

US3172250

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 06:44:49
Query 'Data is required. Please provide.' answered with 'Per Guidelines, ND' (Site from System).	Jessie Downs (b) (4) (b) (4)	28 Aug 2020 21:31:12
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 19:48:01
User entered empty.	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:48:01

US3172250

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:48:01

US3172250

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:48:01

US3172250

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered 'bpm'	System	20 Aug 2020 19:48:01

US3172250

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:48:01

US3172250

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered 'breaths/min'	System	20 Aug 2020 19:48:01

US3172250

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:48:01

US3172250

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered 'mmHg'	System	20 Aug 2020 19:48:01

US3172250

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:48:01

US3172250

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered 'mmHg'	System	20 Aug 2020 19:48:01

US3172250

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06

US3172250

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06

US3172250

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:34:09

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	05 Oct 2020 13:41:21
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:48:20

US3172250

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:34:09

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4) (b) (4)	05 Oct 2020 13:41:21
User entered '20 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:48:20

US3172250

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:09

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:50:26

US3172250

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:09

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:50:26

US3172250

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:09

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:50:26

US3172250

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:09

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:50:26

US3172250

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:09

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:50:26

US3172250

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:09

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:50:26

US3172250

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:09

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:50:26

US3172250

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:09

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:50:26

US3172250

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:09

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:50:26

US3172250

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:09

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:50:26

US3172250

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:09

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:50:26

US3172250

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:09

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:50:26

US3172250

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:09

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:50:26

US3172250

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:09

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '0'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:50:26

US3172250

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:09

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '0'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:50:26

US3172250

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:09

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '0'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:50:26

US3172250

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:09

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '0'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:50:26

US3172250

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:09

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'I'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:50:26

US3172250

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:09

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '0'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:50:26

US3172250

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:09

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '0'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:50:26

US3172250

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:34:09

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:50:26

US3172250

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:34:09

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:48:45

US3172250

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
User entered '20 Aug 2020'	Mariete Rendon (b) (4)	20 Aug 2020 19:48:45
	(b) (4)	

US3172250

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Clinic (Clinic)'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:48:45

US3172250

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:34:09

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User entered 'VISIT1'	System	20 Aug 2020 19:48:45

US3172250

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '20 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	20 Aug 2020 18:24:50

US3172250

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:34:09

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 05:57:55
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:57:54
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Aug 2020 18:24:50
User entered '144372' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	20 Aug 2020 18:24:50

US3172250

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:34:09

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	20 Aug 2020 18:24:50

US3172250

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:34:09

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)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Query 'Should this be yes since subject had history of COPD?' canceled (Site from CRA).	(b) (4), (b) (6)	08 Jan 2021 17:20:09
User opened query 'Should this be yes since subject had history of COPD?' (Site from CRA).	(b) (4), (b) (6)	08 Jan 2021 17:16:53
User entered 'No (N)'	Mariete Rendon (b) (4)	20 Aug 2020 19:54:45
	(b) (4)	

US3172250

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:34:09

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)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:54:45

US3172250

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:34:09

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:54:45

US3172250

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:34:09

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:54:45

US3172250

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:34:09

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:54:45

US3172250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:34:09

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:49:27

US3172250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:34:09

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:49:27

US3172250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:34:09

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:49:27

US3172250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:34:09

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:49:27

US3172250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User accepted default value 'Pre-Dose (PREDOSE)'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:49:27

US3172250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:49:27

US3172250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
User entered '20 Aug 2020'	Mariete Rendon (b) (4)	20 Aug 2020 19:49:27
	(b) (4)	

US3172250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
User entered '11:43'	Mariete Rendon (b) (4)	20 Aug 2020 19:49:27
	(b) (4)	

US3172250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User entered '20 Aug 2020 11:43'	System	20 Aug 2020 19:49:27

US3172250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '36.7' C	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:49:27

US3172250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Oral (Oral)'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:49:27

US3172250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:49:27

US3172250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '87'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:49:27

US3172250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User entered 'bpm'	System	20 Aug 2020 19:49:27

US3172250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '15'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:49:27

US3172250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User entered 'breaths/min'	System	20 Aug 2020 19:49:27

US3172250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '121'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:49:27

US3172250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User entered 'mmHg'	System	20 Aug 2020 19:49:27

US3172250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '79'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:49:27

US3172250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User entered 'mmHg'	System	20 Aug 2020 19:49:27

US3172250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:34:09

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:49:27

US3172250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:34:09

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:49:27

US3172250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User accepted default value 'Post-Dose (POSTDOSE)'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:49:27

US3172250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 21:10:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Aug 2020 21:10:49
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	20 Aug 2020 21:10:49
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 19:49:27
User entered empty.	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:49:27

US3172250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '20 Aug 2020' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	20 Aug 2020 21:10:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:49:27

US3172250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.		21 Aug 2020 05:57:52
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		20 Aug 2020 21:10:49
User entered '16:04' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	20 Aug 2020 21:10:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:49:27

US3172250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User entered '20 Aug 2020 16:04'	System	20 Aug 2020 21:10:49
User entered empty.	System	20 Aug 2020 19:49:27

US3172250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '36.7' C reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	20 Aug 2020 21:10:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:49:27

US3172250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Oral (Oral)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	20 Aug 2020 21:10:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:49:27

US3172250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:49:27

US3172250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '73' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	20 Aug 2020 21:10:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:49:27

US3172250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User entered 'bpm'	System	20 Aug 2020 21:10:49
User entered empty.	System	20 Aug 2020 19:49:27

US3172250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '16' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	20 Aug 2020 21:10:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:49:27

US3172250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User entered 'breaths/min'	System	20 Aug 2020 21:10:49
User entered empty.	System	20 Aug 2020 19:49:27

US3172250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '112' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	20 Aug 2020 21:10:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:49:27

US3172250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User entered 'mmHg'	System	20 Aug 2020 21:10:49
User entered empty.	System	20 Aug 2020 19:49:27

US3172250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '75' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	20 Aug 2020 21:10:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:49:27

US3172250

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User entered 'mmHg'	System	20 Aug 2020 21:10:49
User entered empty.	System	20 Aug 2020 19:49:27

US3172250

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:34:09

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	05 Oct 2020 13:41:35
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:49:35

US3172250

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:34:09

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '20 Aug 2020' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	05 Oct 2020 13:41:35
User entered empty.	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:49:35

US3172250

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:34:09

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:44:17

US3172250

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:34:09

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	20 Aug 2020 19:44:17
	(b) (4)	

US3172250

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:44:17

US3172250

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:34:09

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User entered 'MRNA-1273 OR PLACEBO'	System	20 Aug 2020 19:44:17

US3172250

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:34:09

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '20 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:44:17

US3172250

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:34:09

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '15:34'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:44:17

US3172250

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:34:09

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User entered '20 Aug 2020 15:34'	System	20 Aug 2020 19:44:17

US3172250

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:34:09

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Left Arm (LEFT ARM)'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:44:17

US3172250

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:34:09

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User entered 'ONCE'	System	20 Aug 2020 19:44:17

US3172250

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:34:09

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User entered 'INTRAMUSCULAR'	System	20 Aug 2020 19:44:17

US3172250

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:55:00

US3172250

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '20 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:55:00

US3172250

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:09

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '14:42'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 19:55:00

US3172250

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:09

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User entered '20 Aug 2020 14:42'	System	20 Aug 2020 19:55:00

US3172250

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:34:09

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '20 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 20:00:32

US3172250

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:34:09

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 20:00:32

US3172250

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:34:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 20:00:32

US3172250

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:34:09

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
User entered '14:38'	Mariete Rendon (b) (4)	20 Aug 2020 20:00:32
	(b) (4)	

US3172250

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:34:09

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User entered '20 Aug 2020 14:38'	System	20 Aug 2020 20:00:32

US3172250

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:34:09

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 20:00:32

US3172250

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:34:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 14:48:48
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 20:00:32

US3172250

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:34:09

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered empty; reason for change Data Entry Error	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 14:48:48
User entered '14:38'	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 20:00:32

US3172250

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:34:09

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User entered empty.	System	17 Sep 2020 14:48:48
User entered '20 Aug 2020 14:38'	System	20 Aug 2020 20:00:32

US3172250

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:34:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	20 Aug 2020 21:13:46

US3172250

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:34:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User entered '1'	System	20 Aug 2020 21:13:46

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
Data entry locked.	System	20 Aug 2020 19:44:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-20T16:16:24', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '537812b5-1f7b-4520-8c08-826efc8ee78d'	System	20 Aug 2020 20:16:44
User entered 'Yes (Y)'	System	20 Aug 2020 20:16:44

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-20T16:16:29', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '537812b5-1f7b-4520-8c08-826efc8ee78d'	System	20 Aug 2020 20:16:44
User entered '98.0'	System	20 Aug 2020 20:16:44

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-20T16:16:34', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '537812b5-1f7b-4520-8c08-826efc8ee78d'	System	20 Aug 2020 20:16:44
User entered 'No (N)'	System	20 Aug 2020 20:16:44

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-20T16:16:43', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '537812b5-1f7b-4520-8c08-826efc8ee78d'	System	20 Aug 2020 20:16:44
User entered '20 Aug 2020 16:16'	System	20 Aug 2020 20:16:44

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '20 Aug 2020 15:54'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '20 Aug 2020 18:24'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
Data entry locked.	System	20 Aug 2020 19:44:17
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-20T20:18:37', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'b8359bb9-e004-495e-a515-8c6acf87cd9b'	System	21 Aug 2020 00:20:28
User entered 'Yes (Y)'	System	21 Aug 2020 00:20:28

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-20T20:19:35', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'b8359bb9-e004-495e-a515-8c6acf87cd9b'	System	21 Aug 2020 00:20:28
User entered '98.0'	System	21 Aug 2020 00:20:28

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-20T20:19:40', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'b8359bb9-e004-495e-a515-8c6acf87cd9b'	System	21 Aug 2020 00:20:28
User entered 'Yes (Y)'	System	21 Aug 2020 00:20:28

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-20T20:20:08', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'b8359bb9-e004-495e-a515-8c6acf87cd9b'	System	21 Aug 2020 00:20:28
User entered '0'	System	21 Aug 2020 00:20:28

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'per source no meds taken' (Site from System).	Ipsita Abalokita (b) (4) (b) (4)	03 Sep 2020 14:16:33
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	Mariete Rendon (b) (4) (b) (4)	31 Aug 2020 19:34:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-20T20:20:08', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'b8359bb9-e004-495e-a515-8c6acf87cd9b'	System	21 Aug 2020 00:20:28
User entered '1'	System	21 Aug 2020 00:20:28

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-20T20:20:28', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'b8359bb9-e004-495e-a515-8c6acf87cd9b'	System	21 Aug 2020 00:20:28
User entered '20 Aug 2020 20:20'	System	21 Aug 2020 00:20:28

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '20 Aug 2020 19:19'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
Data entry locked.	System	20 Aug 2020 19:44:17
User entered 'Day 2'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:34:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-21T16:06:39', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '5b934546-5ed8-4835-8348-f1b63ba10fd8'	System	21 Aug 2020 20:07:11
User entered 'Yes (Y)'	System	21 Aug 2020 20:07:11

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:34:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-21T16:06:49', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '5b934546-5ed8-4835-8348-f1b63ba10fd8'	System	21 Aug 2020 20:07:11
User entered '97.8'	System	21 Aug 2020 20:07:11

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-21T16:06:56', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '5b934546-5ed8-4835-8348-f1b63ba10fd8'	System	21 Aug 2020 20:07:11
User entered 'No (N)'	System	21 Aug 2020 20:07:11

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:34:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-21T16:07:10', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '5b934546-5ed8-4835-8348-f1b63ba10fd8'	System	21 Aug 2020 20:07:11
User entered '21 Aug 2020 16:07'	System	21 Aug 2020 20:07:11

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:34:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:34:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
Data entry locked.	System	20 Aug 2020 19:44:17
User entered 'Day 3'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:34:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-22T14:44:25', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '2108f57c-4d78-4a3b-9cd4-dbb9cf334f0c'	System	22 Aug 2020 18:45:05
User entered 'Yes (Y)'	System	22 Aug 2020 18:45:05

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:34:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-22T14:44:46', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '2108f57c-4d78-4a3b-9cd4-dbb9cf334f0c'	System	22 Aug 2020 18:45:05
User entered '98.6'	System	22 Aug 2020 18:45:05

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-22T14:44:52', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '2108f57c-4d78-4a3b-9cd4-dbb9cf334f0c'	System	22 Aug 2020 18:45:05
User entered 'No (N)'	System	22 Aug 2020 18:45:05

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:34:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-22T14:45:01', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '2108f57c-4d78-4a3b-9cd4-dbb9cf334f0c'	System	22 Aug 2020 18:45:05
User entered '22 Aug 2020 14:45'	System	22 Aug 2020 18:45:05

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:34:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:34:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
Data entry locked.	System	20 Aug 2020 19:44:17
User entered 'Day 4'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:34:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-23T12:30:20', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'f826c14d-c36a-48a6-b5b6-ff2bd3510c18'	System	23 Aug 2020 16:31:23
User entered 'Yes (Y)'	System	23 Aug 2020 16:31:23

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:34:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-23T12:31:04', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'f826c14d-c36a-48a6-b5b6-ff2bd3510c18'	System	23 Aug 2020 16:31:23
User entered '98.5'	System	23 Aug 2020 16:31:23

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-23T12:31:11', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'f826c14d-c36a-48a6-b5b6-ff2bd3510c18'	System	23 Aug 2020 16:31:23
User entered 'No (N)'	System	23 Aug 2020 16:31:23

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:34:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-23T12:31:18', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'f826c14d-c36a-48a6-b5b6-ff2bd3510c18'	System	23 Aug 2020 16:31:23
User entered '23 Aug 2020 12:31'	System	23 Aug 2020 16:31:23

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:34:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:34:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
Data entry locked.	System	20 Aug 2020 19:44:17
User entered 'Day 5'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:34:09

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-24T13:22:36', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '247d9526-2f6e-4e94-8d12-efa796d5f04e'	System	24 Aug 2020 17:23:00
User entered 'Yes (Y)'	System	24 Aug 2020 17:23:00

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:34:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-24T13:22:44', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '247d9526-2f6e-4e94-8d12-efa796d5f04e'	System	24 Aug 2020 17:23:00
User entered '97.8'	System	24 Aug 2020 17:23:00

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-24T13:22:51', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '247d9526-2f6e-4e94-8d12-efa796d5f04e'	System	24 Aug 2020 17:23:00
User entered 'No (N)'	System	24 Aug 2020 17:23:00

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:34:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-24T13:22:58', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '247d9526-2f6e-4e94-8d12-efa796d5f04e'	System	24 Aug 2020 17:23:00
User entered '24 Aug 2020 13:22'	System	24 Aug 2020 17:23:00

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:34:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:34:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
Data entry locked.	System	20 Aug 2020 19:44:17
User entered 'Day 6'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:34:09

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-25T13:27:28', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '01f2611c-49c0-4c0b-a66f-c680d8696907'	System	25 Aug 2020 17:27:51
User entered 'Yes (Y)'	System	25 Aug 2020 17:27:51

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:34:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-25T13:27:38', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '01f2611c-49c0-4c0b-a66f-c680d8696907'	System	25 Aug 2020 17:27:51
User entered '98.0'	System	25 Aug 2020 17:27:51

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-25T13:27:46', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '01f2611c-49c0-4c0b-a66f-c680d8696907'	System	25 Aug 2020 17:27:51
User entered 'No (N)'	System	25 Aug 2020 17:27:51

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:34:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-25T13:27:51', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '01f2611c-49c0-4c0b-a66f-c680d8696907'	System	25 Aug 2020 17:27:51
User entered '25 Aug 2020 13:27'	System	25 Aug 2020 17:27:51

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:34:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:34:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
Data entry locked.	System	20 Aug 2020 19:44:17
User entered 'Day 7'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:34:09

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-26T12:10:05', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'd05b8ed6-301c-4a8a-85b4-605f7be79e27'	System	26 Aug 2020 16:10:32
User entered 'Yes (Y)'	System	26 Aug 2020 16:10:32

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:34:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-26T12:10:17', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'd05b8ed6-301c-4a8a-85b4-605f7be79e27'	System	26 Aug 2020 16:10:32
User entered '98.3'	System	26 Aug 2020 16:10:32

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-26T12:10:23', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'd05b8ed6-301c-4a8a-85b4-605f7be79e27'	System	26 Aug 2020 16:10:32
User entered 'No (N)'	System	26 Aug 2020 16:10:32

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:34:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-26T12:10:28', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'd05b8ed6-301c-4a8a-85b4-605f7be79e27'	System	26 Aug 2020 16:10:32
User entered '26 Aug 2020 12:10'	System	26 Aug 2020 16:10:32

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:34:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:34:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
Data entry locked.	System	20 Aug 2020 19:44:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-20T16:16:55', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '2f47595e-c339-41de-9fe6-8577f4ca99cb'	System	20 Aug 2020 20:17:17
User entered 'None (1)'	System	20 Aug 2020 20:17:17

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-20T16:17:02', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '2f47595e-c339-41de-9fe6-8577f4ca99cb'	System	20 Aug 2020 20:17:17
User entered 'No (N)'	System	20 Aug 2020 20:17:17

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-20T16:17:04', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '2f47595e-c339-41de-9fe6-8577f4ca99cb'	System	20 Aug 2020 20:17:17
User entered 'No (N)'	System	20 Aug 2020 20:17:17

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-20T16:17:11', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '2f47595e-c339-41de-9fe6-8577f4ca99cb'	System	20 Aug 2020 20:17:17
User entered 'None (1)'	System	20 Aug 2020 20:17:17

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-20T16:17:16', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '2f47595e-c339-41de-9fe6-8577f4ca99cb'	System	20 Aug 2020 20:17:17
User entered '20 Aug 2020 16:17'	System	20 Aug 2020 20:17:17

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '20 Aug 2020 15:54'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '20 Aug 2020 18:24'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
Data entry locked.	System	20 Aug 2020 19:44:17
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-20T20:20:36', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '327c7cb9-339b-48d9-8259-ca535dee3af2'	System	21 Aug 2020 00:21:07
User entered 'None (1)'	System	21 Aug 2020 00:21:07

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-20T20:20:42', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '327c7cb9-339b-48d9-8259-ca535dee3af2'	System	21 Aug 2020 00:21:07
User entered 'No (N)'	System	21 Aug 2020 00:21:07

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-20T20:20:45', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '327c7cb9-339b-48d9-8259-ca535dee3af2'	System	21 Aug 2020 00:21:07
User entered 'No (N)'	System	21 Aug 2020 00:21:07

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-20T20:20:53', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '327c7cb9-339b-48d9-8259-ca535dee3af2'	System	21 Aug 2020 00:21:07
User entered 'None (1)'	System	21 Aug 2020 00:21:07

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-20T20:21:07', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '327c7cb9-339b-48d9-8259-ca535dee3af2'	System	21 Aug 2020 00:21:07
User entered '20 Aug 2020 20:21'	System	21 Aug 2020 00:21:07

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '20 Aug 2020 19:19'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
Data entry locked.	System	20 Aug 2020 19:44:17
User entered 'Day 2'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:34:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-21T16:07:24', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'c86ea316-d74c-4cab-9cc4-a19c3d0f4355'	System	21 Aug 2020 20:07:46
User entered 'None (1)'	System	21 Aug 2020 20:07:46

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-21T16:07:28', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'c86ea316-d74c-4cab-9cc4-a19c3d0f4355'	System	21 Aug 2020 20:07:46
User entered 'No (N)'	System	21 Aug 2020 20:07:46

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-21T16:07:31', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'c86ea316-d74c-4cab-9cc4-a19c3d0f4355'	System	21 Aug 2020 20:07:46
User entered 'No (N)'	System	21 Aug 2020 20:07:46

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:34:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-21T16:07:36', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'c86ea316-d74c-4cab-9cc4-a19c3d0f4355'	System	21 Aug 2020 20:07:46
User entered 'None (1)'	System	21 Aug 2020 20:07:46

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:34:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-21T16:07:47', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'c86ea316-d74c-4cab-9cc4-a19c3d0f4355'	System	21 Aug 2020 20:07:46
User entered '21 Aug 2020 16:07'	System	21 Aug 2020 20:07:46

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:34:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:34:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
Data entry locked.	System	20 Aug 2020 19:44:17
User entered 'Day 3'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:34:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-22T14:45:12', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '835dfeb1-3a82-4cc7-875c-df3c14aaa4ee'	System	22 Aug 2020 18:45:39
User entered 'None (1)'	System	22 Aug 2020 18:45:39

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:34:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-22T14:45:17', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '835dfeb1-3a82-4cc7-875c-df3c14aaa4ee'	System	22 Aug 2020 18:45:39
User entered 'No (N)'	System	22 Aug 2020 18:45:39

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-22T14:45:21', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '835dfeb1-3a82-4cc7-875c-df3c14aaa4ee'	System	22 Aug 2020 18:45:39
User entered 'No (N)'	System	22 Aug 2020 18:45:39

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:34:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-22T14:45:26', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '835dfeb1-3a82-4cc7-875c-df3c14aaa4ee'	System	22 Aug 2020 18:45:39
User entered 'None (1)'	System	22 Aug 2020 18:45:39

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:34:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-22T14:45:36', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '835dfeb1-3a82-4cc7-875c-df3c14aaa4ee'	System	22 Aug 2020 18:45:39
User entered '22 Aug 2020 14:45'	System	22 Aug 2020 18:45:39

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:34:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:34:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
Data entry locked.	System	20 Aug 2020 19:44:17
User entered 'Day 4'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:34:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-23T12:31:30', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '3ef46ebe-0bc0-4781-b72a-d677e224b8b9'	System	23 Aug 2020 16:31:56
User entered 'None (1)'	System	23 Aug 2020 16:31:56

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:34:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-23T12:31:35', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '3ef46ebe-0bc0-4781-b72a-d677e224b8b9'	System	23 Aug 2020 16:31:56
User entered 'No (N)'	System	23 Aug 2020 16:31:56

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-23T12:31:39', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '3ef46ebe-0bc0-4781-b72a-d677e224b8b9'	System	23 Aug 2020 16:31:56
User entered 'No (N)'	System	23 Aug 2020 16:31:56

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:34:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-23T12:31:45', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '3ef46ebe-0bc0-4781-b72a-d677e224b8b9'	System	23 Aug 2020 16:31:56
User entered 'None (1)'	System	23 Aug 2020 16:31:56

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:34:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-23T12:31:52', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '3ef46ebe-0bc0-4781-b72a-d677e224b8b9'	System	23 Aug 2020 16:31:56
User entered '23 Aug 2020 12:31'	System	23 Aug 2020 16:31:56

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:34:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:34:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
Data entry locked.	System	20 Aug 2020 19:44:17
User entered 'Day 5'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:34:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-24T13:23:04', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '83497082-2213-41c0-928d-8ca84e771021'	System	24 Aug 2020 17:23:27
User entered 'None (1)'	System	24 Aug 2020 17:23:27

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-24T13:23:08', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '83497082-2213-41c0-928d-8ca84e771021'	System	24 Aug 2020 17:23:27
User entered 'No (N)'	System	24 Aug 2020 17:23:27

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-24T13:23:11', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '83497082-2213-41c0-928d-8ca84e771021'	System	24 Aug 2020 17:23:27
User entered 'No (N)'	System	24 Aug 2020 17:23:27

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:34:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-24T13:23:16', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '83497082-2213-41c0-928d-8ca84e771021'	System	24 Aug 2020 17:23:27
User entered 'None (1)'	System	24 Aug 2020 17:23:27

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:34:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-24T13:23:24', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '83497082-2213-41c0-928d-8ca84e771021'	System	24 Aug 2020 17:23:27
User entered '24 Aug 2020 13:23'	System	24 Aug 2020 17:23:27

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:34:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:34:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
Data entry locked.	System	20 Aug 2020 19:44:17
User entered 'Day 6'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:34:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-25T13:27:58', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'b5ff0a4e-325e-4da4-b307-b5cc8ab8eff8'	System	25 Aug 2020 17:28:19
User entered 'None (1)'	System	25 Aug 2020 17:28:19

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:34:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-25T13:28:02', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'b5ff0a4e-325e-4da4-b307-b5cc8ab8eff8'	System	25 Aug 2020 17:28:19
User entered 'No (N)'	System	25 Aug 2020 17:28:19

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:34:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-25T13:28:05', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'b5ff0a4e-325e-4da4-b307-b5cc8ab8eff8'	System	25 Aug 2020 17:28:19
User entered 'No (N)'	System	25 Aug 2020 17:28:19

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:34:09

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-25T13:28:11', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'b5ff0a4e-325e-4da4-b307-b5cc8ab8eff8'	System	25 Aug 2020 17:28:19
User entered 'None (1)'	System	25 Aug 2020 17:28:19

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:34:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-25T13:28:16', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'b5ff0a4e-325e-4da4-b307-b5cc8ab8eff8'	System	25 Aug 2020 17:28:19
User entered '25 Aug 2020 13:28'	System	25 Aug 2020 17:28:19

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:34:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:34:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
Data entry locked.	System	20 Aug 2020 19:44:17
User entered 'Day 7'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:34:09

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-26T12:10:34', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '11fccbd1-908d-4bc6-be7a-1561bc6146ea'	System	26 Aug 2020 16:11:02
User entered 'None (1)'	System	26 Aug 2020 16:11:02

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:34:09

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-26T12:10:38', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '11fccbd1-908d-4bc6-be7a-1561bc6146ea'	System	26 Aug 2020 16:11:02
User entered 'No (N)'	System	26 Aug 2020 16:11:02

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:34:09

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-26T12:10:41', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '11fccbd1-908d-4bc6-be7a-1561bc6146ea'	System	26 Aug 2020 16:11:02
User entered 'No (N)'	System	26 Aug 2020 16:11:02

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:34:09

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-26T12:10:49', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '11fccbd1-908d-4bc6-be7a-1561bc6146ea'	System	26 Aug 2020 16:11:02
User entered 'None (1)'	System	26 Aug 2020 16:11:02

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:34:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-26T12:10:56', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '11fccbd1-908d-4bc6-be7a-1561bc6146ea'	System	26 Aug 2020 16:11:02
User entered '26 Aug 2020 12:10'	System	26 Aug 2020 16:11:02

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:34:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:34:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
Data entry locked.	System	20 Aug 2020 19:44:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-20T16:17:28', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '4e8060d2-1277-42b7-8ea2-a46cac819276'	System	20 Aug 2020 20:17:50
User entered 'None (0)'	System	20 Aug 2020 20:17:50

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-20T16:17:30', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '4e8060d2-1277-42b7-8ea2-a46cac819276'	System	20 Aug 2020 20:17:50
User entered 'None (0)'	System	20 Aug 2020 20:17:50

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-20T16:17:32', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '4e8060d2-1277-42b7-8ea2-a46cac819276'	System	20 Aug 2020 20:17:50
User entered 'None (0)'	System	20 Aug 2020 20:17:50

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-20T16:17:34', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '4e8060d2-1277-42b7-8ea2-a46cac819276'	System	20 Aug 2020 20:17:50
User entered 'None (0)'	System	20 Aug 2020 20:17:50

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-20T16:17:36', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '4e8060d2-1277-42b7-8ea2-a46cac819276'	System	20 Aug 2020 20:17:50
User entered 'None (0)'	System	20 Aug 2020 20:17:50

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-20T16:17:38', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '4e8060d2-1277-42b7-8ea2-a46cac819276'	System	20 Aug 2020 20:17:50
User entered 'None (0)'	System	20 Aug 2020 20:17:50

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-20T16:17:47', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '4e8060d2-1277-42b7-8ea2-a46cac819276'	System	20 Aug 2020 20:17:50
User entered 'No (N)'	System	20 Aug 2020 20:17:50

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-20T16:17:49', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '4e8060d2-1277-42b7-8ea2-a46cac819276'	System	20 Aug 2020 20:17:50
User entered '20 Aug 2020 16:17'	System	20 Aug 2020 20:17:50

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '20 Aug 2020 15:54'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '20 Aug 2020 18:24'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
Data entry locked.	System	20 Aug 2020 19:44:17
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-20T20:21:13', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '05140d11-0dc1-4555-a1ed-29d6a7f8a6c6'	System	21 Aug 2020 00:22:09
User entered 'None (0)'	System	21 Aug 2020 00:22:09

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-20T20:21:17', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '05140d11-0dc1-4555-a1ed-29d6a7f8a6c6'	System	21 Aug 2020 00:22:09
User entered 'None (0)'	System	21 Aug 2020 00:22:09

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-20T20:21:21', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '05140d11-0dc1-4555-a1ed-29d6a7f8a6c6'	System	21 Aug 2020 00:22:09
User entered 'None (0)'	System	21 Aug 2020 00:22:09

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-20T20:21:25', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '05140d11-0dc1-4555-a1ed-29d6a7f8a6c6'	System	21 Aug 2020 00:22:09
User entered 'None (0)'	System	21 Aug 2020 00:22:09

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-20T20:21:29', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '05140d11-0dc1-4555-a1ed-29d6a7f8a6c6'	System	21 Aug 2020 00:22:09
User entered 'None (0)'	System	21 Aug 2020 00:22:09

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-20T20:21:32', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '05140d11-0dc1-4555-a1ed-29d6a7f8a6c6'	System	21 Aug 2020 00:22:09
User entered 'None (0)'	System	21 Aug 2020 00:22:09

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-20T20:21:59', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '05140d11-0dc1-4555-a1ed-29d6a7f8a6c6'	System	21 Aug 2020 00:22:09
User entered 'No (N)'	System	21 Aug 2020 00:22:09

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-20T20:22:09', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '05140d11-0dc1-4555-a1ed-29d6a7f8a6c6'	System	21 Aug 2020 00:22:09
User entered '20 Aug 2020 20:22'	System	21 Aug 2020 00:22:09

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '20 Aug 2020 19:19'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
Data entry locked.	System	20 Aug 2020 19:44:17
User entered 'Day 2'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-21T16:07:54', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '5c211883-fdc1-49cd-bb3f-7a3ef60ffb0e'	System	21 Aug 2020 20:08:24
User entered 'None (0)'	System	21 Aug 2020 20:08:24

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-21T16:07:57', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '5c211883-fdc1-49cd-bb3f-7a3ef60ffb0e'	System	21 Aug 2020 20:08:24
User entered 'None (0)'	System	21 Aug 2020 20:08:24

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-21T16:08:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '5c211883-fdc1-49cd-bb3f-7a3ef60ffb0e'	System	21 Aug 2020 20:08:24
User entered 'None (0)'	System	21 Aug 2020 20:08:24

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-21T16:08:04', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '5c211883-fdc1-49cd-bb3f-7a3ef60ffb0e'	System	21 Aug 2020 20:08:24
User entered 'None (0)'	System	21 Aug 2020 20:08:24

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-21T16:08:07', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '5c211883-fdc1-49cd-bb3f-7a3ef60ffb0e'	System	21 Aug 2020 20:08:24
User entered 'None (0)'	System	21 Aug 2020 20:08:24

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-21T16:08:09', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '5c211883-fdc1-49cd-bb3f-7a3ef60ffb0e'	System	21 Aug 2020 20:08:24
User entered 'None (0)'	System	21 Aug 2020 20:08:24

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-21T16:08:14', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '5c211883-fdc1-49cd-bb3f-7a3ef60ffb0e'	System	21 Aug 2020 20:08:24
User entered 'No (N)'	System	21 Aug 2020 20:08:24

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-21T16:08:25', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '5c211883-fdc1-49cd-bb3f-7a3ef60ffb0e'	System	21 Aug 2020 20:08:24
User entered '21 Aug 2020 16:08'	System	21 Aug 2020 20:08:24

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
Data entry locked.	System	20 Aug 2020 19:44:17
User entered 'Day 3'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-22T14:45:44', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'a31b56a2-8ddd-480a-85e5-644dea91d6d0'	System	22 Aug 2020 18:46:33
User entered 'None (0)'	System	22 Aug 2020 18:46:33

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-22T14:45:48', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'a31b56a2-8ddd-480a-85e5-644dea91d6d0'	System	22 Aug 2020 18:46:33
User entered 'None (0)'	System	22 Aug 2020 18:46:33

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-22T14:45:52', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'a31b56a2-8ddd-480a-85e5-644dea91d6d0'	System	22 Aug 2020 18:46:33
User entered 'None (0)'	System	22 Aug 2020 18:46:33

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-22T14:46:09', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'a31b56a2-8ddd-480a-85e5-644dea91d6d0'	System	22 Aug 2020 18:46:33
User entered 'None (0)'	System	22 Aug 2020 18:46:33

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-22T14:46:13', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'a31b56a2-8ddd-480a-85e5-644dea91d6d0'	System	22 Aug 2020 18:46:33
User entered 'None (0)'	System	22 Aug 2020 18:46:33

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-22T14:46:16', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'a31b56a2-8ddd-480a-85e5-644dea91d6d0'	System	22 Aug 2020 18:46:33
User entered 'None (0)'	System	22 Aug 2020 18:46:33

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-22T14:46:22', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'a31b56a2-8ddd-480a-85e5-644dea91d6d0'	System	22 Aug 2020 18:46:33
User entered 'No (N)'	System	22 Aug 2020 18:46:33

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-22T14:46:29', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'a31b56a2-8ddd-480a-85e5-644dea91d6d0'	System	22 Aug 2020 18:46:33
User entered '22 Aug 2020 14:46'	System	22 Aug 2020 18:46:33

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
Data entry locked.	System	20 Aug 2020 19:44:17
User entered 'Day 4'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-23T12:31:57', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '87ef3c02-5167-4197-a15f-8beace157d4a'	System	23 Aug 2020 16:32:37
User entered 'None (0)'	System	23 Aug 2020 16:32:37

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-23T12:32:01', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '87ef3c02-5167-4197-a15f-8beace157d4a'	System	23 Aug 2020 16:32:37
User entered 'None (0)'	System	23 Aug 2020 16:32:37

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-23T12:32:05', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '87ef3c02-5167-4197-a15f-8beace157d4a'	System	23 Aug 2020 16:32:37
User entered 'None (0)'	System	23 Aug 2020 16:32:37

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-23T12:32:09', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '87ef3c02-5167-4197-a15f-8beace157d4a'	System	23 Aug 2020 16:32:37
User entered 'None (0)'	System	23 Aug 2020 16:32:37

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-23T12:32:13', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '87ef3c02-5167-4197-a15f-8beace157d4a'	System	23 Aug 2020 16:32:37
User entered 'None (0)'	System	23 Aug 2020 16:32:37

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-23T12:32:16', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '87ef3c02-5167-4197-a15f-8beace157d4a'	System	23 Aug 2020 16:32:37
User entered 'None (0)'	System	23 Aug 2020 16:32:37

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-23T12:32:26', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '87ef3c02-5167-4197-a15f-8beace157d4a'	System	23 Aug 2020 16:32:37
User entered 'No (N)'	System	23 Aug 2020 16:32:37

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-23T12:32:33', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '87ef3c02-5167-4197-a15f-8beace157d4a'	System	23 Aug 2020 16:32:37
User entered '23 Aug 2020 12:32'	System	23 Aug 2020 16:32:37

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
Data entry locked.	System	20 Aug 2020 19:44:17
User entered 'Day 5'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-24T13:23:36', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'c5060503-070c-4b37-91b1-36c6bf291dcc'	System	24 Aug 2020 17:24:04
User entered 'None (0)'	System	24 Aug 2020 17:24:04

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-24T13:23:40', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'c5060503-070c-4b37-91b1-36c6bf291dcc'	System	24 Aug 2020 17:24:04
User entered 'None (0)'	System	24 Aug 2020 17:24:04

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-24T13:23:44', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'c5060503-070c-4b37-91b1-36c6bf291dcc'	System	24 Aug 2020 17:24:04
User entered 'None (0)'	System	24 Aug 2020 17:24:04

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-24T13:23:48', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'c5060503-070c-4b37-91b1-36c6bf291dcc'	System	24 Aug 2020 17:24:04
User entered 'None (0)'	System	24 Aug 2020 17:24:04

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-24T13:23:51', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'c5060503-070c-4b37-91b1-36c6bf291dcc'	System	24 Aug 2020 17:24:04
User entered 'None (0)'	System	24 Aug 2020 17:24:04

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-24T13:23:53', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'c5060503-070c-4b37-91b1-36c6bf291dcc'	System	24 Aug 2020 17:24:04
User entered 'None (0)'	System	24 Aug 2020 17:24:04

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-24T13:23:57', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'c5060503-070c-4b37-91b1-36c6bf291dcc'	System	24 Aug 2020 17:24:04
User entered 'No (N)'	System	24 Aug 2020 17:24:04

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-24T13:24:03', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'c5060503-070c-4b37-91b1-36c6bf291dcc'	System	24 Aug 2020 17:24:04
User entered '24 Aug 2020 13:24'	System	24 Aug 2020 17:24:04

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
Data entry locked.	System	20 Aug 2020 19:44:17
User entered 'Day 6'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-25T13:28:22', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'd0d0e53f-8c37-49a9-8760-116dccdda56b'	System	25 Aug 2020 17:28:48
User entered 'None (0)'	System	25 Aug 2020 17:28:48

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-25T13:28:24', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'd0d0e53f-8c37-49a9-8760-116dccdda56b'	System	25 Aug 2020 17:28:48
User entered 'None (0)'	System	25 Aug 2020 17:28:48

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-25T13:28:28', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'd0d0e53f-8c37-49a9-8760-116dccdda56b'	System	25 Aug 2020 17:28:48
User entered 'None (0)'	System	25 Aug 2020 17:28:48

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-25T13:28:32', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'd0d0e53f-8c37-49a9-8760-116dccdda56b'	System	25 Aug 2020 17:28:48
User entered 'None (0)'	System	25 Aug 2020 17:28:48

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-25T13:28:35', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'd0d0e53f-8c37-49a9-8760-116dccdda56b'	System	25 Aug 2020 17:28:48
User entered 'None (0)'	System	25 Aug 2020 17:28:48

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-25T13:28:37', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'd0d0e53f-8c37-49a9-8760-116dccdda56b'	System	25 Aug 2020 17:28:48
User entered 'None (0)'	System	25 Aug 2020 17:28:48

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-25T13:28:43', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'd0d0e53f-8c37-49a9-8760-116dccdda56b'	System	25 Aug 2020 17:28:48
User entered 'No (N)'	System	25 Aug 2020 17:28:48

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-25T13:28:47', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'd0d0e53f-8c37-49a9-8760-116dccdda56b'	System	25 Aug 2020 17:28:48
User entered '25 Aug 2020 13:28'	System	25 Aug 2020 17:28:48

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
Data entry locked.	System	20 Aug 2020 19:44:17
User entered 'Day 7'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-26T12:11:02', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '09df83a6-51f4-4dbc-a8cf-ecf3453cddc1'	System	26 Aug 2020 16:11:38
User entered 'None (0)'	System	26 Aug 2020 16:11:38

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-26T12:11:05', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '09df83a6-51f4-4dbc-a8cf-ecf3453cddc1'	System	26 Aug 2020 16:11:38
User entered 'None (0)'	System	26 Aug 2020 16:11:38

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-26T12:11:08', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '09df83a6-51f4-4dbc-a8cf-ecf3453cddc1'	System	26 Aug 2020 16:11:38
User entered 'None (0)'	System	26 Aug 2020 16:11:38

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-26T12:11:11', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '09df83a6-51f4-4dbc-a8cf-ecf3453cddc1'	System	26 Aug 2020 16:11:38
User entered 'None (0)'	System	26 Aug 2020 16:11:38

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-26T12:11:13', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '09df83a6-51f4-4dbc-a8cf-ecf3453cddc1'	System	26 Aug 2020 16:11:38
User entered 'None (0)'	System	26 Aug 2020 16:11:38

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-26T12:11:16', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '09df83a6-51f4-4dbc-a8cf-ecf3453cddc1'	System	26 Aug 2020 16:11:38
User entered 'None (0)'	System	26 Aug 2020 16:11:38

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-26T12:11:20', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '09df83a6-51f4-4dbc-a8cf-ecf3453cddc1'	System	26 Aug 2020 16:11:38
User entered 'No (N)'	System	26 Aug 2020 16:11:38

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-08-26T12:11:23', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '09df83a6-51f4-4dbc-a8cf-ecf3453cddc1'	System	26 Aug 2020 16:11:38
User entered '26 Aug 2020 12:11'	System	26 Aug 2020 16:11:38

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 19:44:17

US3172250

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 19:44:17

US3172250

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	01 Sep 2020 15:35:48

US3172250

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:09

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '28 Aug 2020'	Jessie Downs (b) (4) (b) (4)	01 Sep 2020 15:35:48

US3172250

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	01 Sep 2020 15:35:48

US3172250

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	01 Sep 2020 15:35:48

US3172250

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	01 Sep 2020 15:35:53

US3172250

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User entered 'I'	System	01 Sep 2020 15:35:53

US3172250

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	08 Sep 2020 15:51:46

US3172250

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:09

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
User entered '04 Sep 2020'	Jessie Downs (b) (4)	08 Sep 2020 15:51:46
	(b) (4)	

US3172250

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	08 Sep 2020 15:51:46

US3172250

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	08 Sep 2020 15:51:46

US3172250

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	08 Sep 2020 15:51:50

US3172250

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User entered 'I'	System	08 Sep 2020 15:51:50

US3172250

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	16 Sep 2020 14:13:22

US3172250

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:09

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '10 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	16 Sep 2020 14:13:22

US3172250

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Contact Made (CONTACT MADE)'	Mariete Rendon (b) (4) (b) (4)	16 Sep 2020 14:13:22

US3172250

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Sep 2020 14:13:22

US3172250

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	16 Sep 2020 14:13:28

US3172250

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User entered 'I'	System	16 Sep 2020 14:13:28

US3172250

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:34:09

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 15:34:08

US3172250

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:34:09

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '18 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 15:34:08

US3172250

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:34:09

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Clinic (Clinic)'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 15:34:08

US3172250

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:34:09

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User entered 'VISIT2'	System	21 Sep 2020 15:34:08

US3172250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User accepted default value 'Pre-Dose (PREDOSE)'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 15:35:16

US3172250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 15:35:16

US3172250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '18 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 15:35:16

US3172250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '09:55'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 15:35:16

US3172250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User entered '18 Sep 2020 09:55'	System	21 Sep 2020 15:35:16

US3172250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '36.8' C	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 15:35:16

US3172250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Oral (Oral)'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 15:35:16

US3172250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 15:35:16

US3172250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '71'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 15:35:16

US3172250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User entered 'bpm'	System	21 Sep 2020 15:35:16

US3172250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '16'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 15:35:16

US3172250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User entered 'breaths/min'	System	21 Sep 2020 15:35:16

US3172250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '126'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 15:35:16

US3172250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User entered 'mmHg'	System	21 Sep 2020 15:35:16

US3172250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '83'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 15:35:16

US3172250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User entered 'mmHg'	System	21 Sep 2020 15:35:16

US3172250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User accepted default value 'Post-Dose (POSTDOSE)'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 15:35:16

US3172250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 15:35:16

US3172250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '18 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 15:35:16

US3172250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '12:43'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 15:35:16

US3172250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User entered '18 Sep 2020 12:43'	System	21 Sep 2020 15:35:16

US3172250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '37.0' C	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 15:35:16

US3172250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Oral (Oral)'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 15:35:16

US3172250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 15:35:16

US3172250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '64'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 15:35:16

US3172250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User entered 'bpm'	System	21 Sep 2020 15:35:16

US3172250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '14'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 15:35:16

US3172250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User entered 'breaths/min'	System	21 Sep 2020 15:35:16

US3172250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '117'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 15:35:16

US3172250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User entered 'mmHg'	System	21 Sep 2020 15:35:16

US3172250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '75'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 15:35:16

US3172250

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User entered 'mmHg'	System	21 Sep 2020 15:35:16

US3172250

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:34:09

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 15:35:25

US3172250

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:34:09

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '18 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 15:35:25

US3172250

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:34:09

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 16:23:33

US3172250

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:34:09

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 16:23:33

US3172250

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:34:09

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 16:23:33

US3172250

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:34:09

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User entered 'MRNA-1273 OR PLACEBO'	System	18 Sep 2020 16:23:33

US3172250

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:34:09

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '18 Sep 2020'	(b) (4), (b) (6)	18 Sep 2020 16:23:33

US3172250

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:34:09

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '12:13'	(b) (4), (b) (6)	18 Sep 2020 16:23:33

US3172250

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:34:09

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User entered '18 Sep 2020 12:13'	System	18 Sep 2020 16:23:33

US3172250

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:34:09

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	18 Sep 2020 16:23:33

US3172250

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:34:09

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User entered 'ONCE'	System	18 Sep 2020 16:23:33

US3172250

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:34:09

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User entered 'INTRAMUSCULAR'	System	18 Sep 2020 16:23:33

US3172250

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 15:35:40

US3172250

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:09

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '18 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 15:35:40

US3172250

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:09

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '11:50'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 15:35:40

US3172250

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:09

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User entered '18 Sep 2020 11:50'	System	21 Sep 2020 15:35:40

US3172250

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:34:09

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '18 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 15:35:53

US3172250

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:34:09

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 15:35:53

US3172250

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:34:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 15:35:53

US3172250

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:34:09

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '11:46'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 15:35:53

US3172250

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:34:09

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User entered '18 Sep 2020 11:46'	System	21 Sep 2020 15:35:53

US3172250

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:34:09

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 15:35:53

US3172250

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:34:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 15:35:53

US3172250

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:34:09

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 15:35:53

US3172250

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:34:09

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User entered empty.	System	21 Sep 2020 15:35:53

US3172250

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 15:36:00

US3172250

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User entered 'I'	System	21 Sep 2020 15:36:00

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
Data entry locked.	System	18 Sep 2020 16:23:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-18T12:44:39', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '8b62924f-5a04-47c9-bca7-3db6eb092154'	System	18 Sep 2020 16:45:00
User entered 'Yes (Y)'	System	18 Sep 2020 16:45:00

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-18T12:44:47', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '8b62924f-5a04-47c9-bca7-3db6eb092154'	System	18 Sep 2020 16:45:00
User entered '98.6'	System	18 Sep 2020 16:45:00

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-18T12:44:52', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '8b62924f-5a04-47c9-bca7-3db6eb092154'	System	18 Sep 2020 16:45:00
User entered 'No (N)'	System	18 Sep 2020 16:45:00

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-18T12:44:57', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '8b62924f-5a04-47c9-bca7-3db6eb092154'	System	18 Sep 2020 16:45:00
User entered '18 Sep 2020 12:44'	System	18 Sep 2020 16:45:00

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '18 Sep 2020 12:33'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '18 Sep 2020 15:03'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
Data entry locked.	System	18 Sep 2020 16:23:33
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-18T21:09:21', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'b34f3ae9-44e5-4fd8-b3f2-c5acc035170c'	System	19 Sep 2020 01:09:40
User entered 'Yes (Y)'	System	19 Sep 2020 01:09:40

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-18T21:09:29', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'b34f3ae9-44e5-4fd8-b3f2-c5acc035170c'	System	19 Sep 2020 01:09:40
User entered '98.3'	System	19 Sep 2020 01:09:40

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-18T21:09:34', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'b34f3ae9-44e5-4fd8-b3f2-c5acc035170c'	System	19 Sep 2020 01:09:40
User entered 'No (N)'	System	19 Sep 2020 01:09:40

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-18T21:09:39', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'b34f3ae9-44e5-4fd8-b3f2-c5acc035170c'	System	19 Sep 2020 01:09:40
User entered '18 Sep 2020 21:09'	System	19 Sep 2020 01:09:40

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '18 Sep 2020 15:58'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
Data entry locked.	System	18 Sep 2020 16:23:33
User entered 'Day 2'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:34:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-19T21:31:39', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '75714b21-5534-4063-92bc-84c3ec3b52e3'	System	20 Sep 2020 01:32:06
User entered 'Yes (Y)'	System	20 Sep 2020 01:32:06

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:34:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-19T21:31:47', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '75714b21-5534-4063-92bc-84c3ec3b52e3'	System	20 Sep 2020 01:32:06
User entered '98.6'	System	20 Sep 2020 01:32:06

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:34:09

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-19T21:31:52', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '75714b21-5534-4063-92bc-84c3ec3b52e3'	System	20 Sep 2020 01:32:06
User entered 'No (N)'	System	20 Sep 2020 01:32:06

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:34:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-19T21:31:59', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '75714b21-5534-4063-92bc-84c3ec3b52e3'	System	20 Sep 2020 01:32:06
User entered '19 Sep 2020 21:31'	System	20 Sep 2020 01:32:06

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:34:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:34:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
Data entry locked.	System	18 Sep 2020 16:23:33
User entered 'Day 3'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:34:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-20T21:39:58', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '582f1531-1a2a-43bb-9642-c8552b5aa368'	System	21 Sep 2020 01:40:19
User entered 'Yes (Y)'	System	21 Sep 2020 01:40:19

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:34:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-20T21:40:05', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '582f1531-1a2a-43bb-9642-c8552b5aa368'	System	21 Sep 2020 01:40:19
User entered '97.8'	System	21 Sep 2020 01:40:19

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:34:09

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-20T21:40:11', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '582f1531-1a2a-43bb-9642-c8552b5aa368'	System	21 Sep 2020 01:40:19
User entered 'No (N)'	System	21 Sep 2020 01:40:19

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:34:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-20T21:40:18', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '582f1531-1a2a-43bb-9642-c8552b5aa368'	System	21 Sep 2020 01:40:19
User entered '20 Sep 2020 21:40'	System	21 Sep 2020 01:40:19

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:34:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:34:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
Data entry locked.	System	18 Sep 2020 16:23:33
User entered 'Day 4'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:34:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-21T14:11:49', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '9a6a8658-7ba9-41d0-bd5e-70c1bf033e13'	System	21 Sep 2020 18:12:12
User entered 'Yes (Y)'	System	21 Sep 2020 18:12:12

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:34:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-21T14:11:57', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '9a6a8658-7ba9-41d0-bd5e-70c1bf033e13' User entered '97.7'	System	21 Sep 2020 18:12:12

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:34:09

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-21T14:12:03', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '9a6a8658-7ba9-41d0-bd5e-70c1bf033e13'	System	21 Sep 2020 18:12:12
User entered 'No (N)'	System	21 Sep 2020 18:12:12

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:34:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-21T14:12:10', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '9a6a8658-7ba9-41d0-bd5e-70c1bf033e13'	System	21 Sep 2020 18:12:12
User entered '21 Sep 2020 14:12'	System	21 Sep 2020 18:12:12

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:34:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:34:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
Data entry locked.	System	18 Sep 2020 16:23:33
User entered 'Day 5'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:34:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-22T13:33:53', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '5a84a959-e1c8-4bc9-9b28-28ff137b511b'	System	22 Sep 2020 17:34:08
User entered 'Yes (Y)'	System	22 Sep 2020 17:34:08

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:34:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-22T13:33:59', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '5a84a959-e1c8-4bc9-9b28-28ff137b511b'	System	22 Sep 2020 17:34:08
User entered '96.8'	System	22 Sep 2020 17:34:08

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:34:09

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-22T13:34:05', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '5a84a959-e1c8-4bc9-9b28-28ff137b511b'	System	22 Sep 2020 17:34:08
User entered 'No (N)'	System	22 Sep 2020 17:34:08

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:34:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-22T13:34:08', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '5a84a959-e1c8-4bc9-9b28-28ff137b511b'	System	22 Sep 2020 17:34:08
User entered '22 Sep 2020 13:34'	System	22 Sep 2020 17:34:08

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:34:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:34:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
Data entry locked.	System	18 Sep 2020 16:23:33
User entered 'Day 6'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:34:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-23T12:04:28', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '15c9a201-1cac-4c51-a66f-5c2ce3cffee6'	System	23 Sep 2020 16:05:40
User entered 'Yes (Y)'	System	23 Sep 2020 16:05:40

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:34:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-23T12:04:34', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '15c9a201-1cac-4c51-a66f-5c2ce3cffae6'	System	23 Sep 2020 16:05:40
User entered '97.8'	System	23 Sep 2020 16:05:40

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:34:09

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-23T12:04:40', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '15c9a201-1cac-4c51-a66f-5c2ce3cffae6'	System	23 Sep 2020 16:05:40
User entered 'No (N)'	System	23 Sep 2020 16:05:40

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:34:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-23T12:04:44', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '15c9a201-1cac-4c51-a66f-5c2ce3cffae6'	System	23 Sep 2020 16:05:40
User entered '23 Sep 2020 12:04'	System	23 Sep 2020 16:05:40

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:34:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:34:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
Data entry locked.	System	18 Sep 2020 16:23:33
User entered 'Day 7'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:34:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-24T13:07:04', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'ce4d2829-cf19-47fb-b586-2a44f93ce09d'	System	24 Sep 2020 17:07:26
User entered 'Yes (Y)'	System	24 Sep 2020 17:07:26

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:34:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-24T13:07:14', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'ce4d2829-cf19-47fb-b586-2a44f93ce09d'	System	24 Sep 2020 17:07:26
User entered '97.3'	System	24 Sep 2020 17:07:26

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:34:09

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-24T13:07:18', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'ce4d2829-cf19-47fb-b586-2a44f93ce09d'	System	24 Sep 2020 17:07:26
User entered 'No (N)'	System	24 Sep 2020 17:07:26

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:34:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-24T13:07:22', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'ce4d2829-cf19-47fb-b586-2a44f93ce09d'	System	24 Sep 2020 17:07:26
User entered '24 Sep 2020 13:07'	System	24 Sep 2020 17:07:26

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:34:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:34:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
Data entry locked.	System	18 Sep 2020 16:23:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-18T12:45:09', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '4cd51a5d-1c7a-4e8f-8f36-6c55b7e7d047'	System	18 Sep 2020 16:45:31
User entered 'None (1)'	System	18 Sep 2020 16:45:31

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-18T12:45:13', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '4cd51a5d-1c7a-4e8f-8f36-6c55b7e7d047'	System	18 Sep 2020 16:45:31
User entered 'No (N)'	System	18 Sep 2020 16:45:31

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-18T12:45:16', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '4cd51a5d-1c7a-4e8f-8f36-6c55b7e7d047'	System	18 Sep 2020 16:45:31
User entered 'No (N)'	System	18 Sep 2020 16:45:31

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-18T12:45:21', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '4cd51a5d-1c7a-4e8f-8f36-6c55b7e7d047'	System	18 Sep 2020 16:45:31
User entered 'None (1)'	System	18 Sep 2020 16:45:31

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-18T12:45:30', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '4cd51a5d-1c7a-4e8f-8f36-6c55b7e7d047'	System	18 Sep 2020 16:45:31
User entered '18 Sep 2020 12:45'	System	18 Sep 2020 16:45:31

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '18 Sep 2020 12:33'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '18 Sep 2020 15:03'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
Data entry locked.	System	18 Sep 2020 16:23:33
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-18T21:09:47', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'fcbce24b-9e64-432b-a2a6-f6a55c6e4802'	System	19 Sep 2020 01:10:04
User entered 'None (1)'	System	19 Sep 2020 01:10:04

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-18T21:09:51', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'fcbce24b-9e64-432b-a2a6-f6a55c6e4802'	System	19 Sep 2020 01:10:04
User entered 'No (N)'	System	19 Sep 2020 01:10:04

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-18T21:09:54', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'fcbce24b-9e64-432b-a2a6-f6a55c6e4802'	System	19 Sep 2020 01:10:04
User entered 'No (N)'	System	19 Sep 2020 01:10:04

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-18T21:09:59', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'fcbce24b-9e64-432b-a2a6-f6a55c6e4802'	System	19 Sep 2020 01:10:04
User entered 'None (1)'	System	19 Sep 2020 01:10:04

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-18T21:10:04', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'fcbce24b-9e64-432b-a2a6-f6a55c6e4802'	System	19 Sep 2020 01:10:04
User entered '18 Sep 2020 21:10'	System	19 Sep 2020 01:10:04

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '18 Sep 2020 15:58'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
Data entry locked.	System	18 Sep 2020 16:23:33
User entered 'Day 2'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:34:09

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-19T21:32:04', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'd1b0c24a-cd9b-4f89-9d94-8c9a58fece9f'	System	20 Sep 2020 01:32:26
User entered 'None (1)'	System	20 Sep 2020 01:32:26

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:34:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-19T21:32:08', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'd1b0c24a-cd9b-4f89-9d94-8c9a58fece9f'	System	20 Sep 2020 01:32:26
User entered 'No (N)'	System	20 Sep 2020 01:32:26

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:34:09

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-19T21:32:11', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'd1b0c24a-cd9b-4f89-9d94-8c9a58fece9f'	System	20 Sep 2020 01:32:26
User entered 'No (N)'	System	20 Sep 2020 01:32:26

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:34:09

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-19T21:32:17', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'd1b0c24a-cd9b-4f89-9d94-8c9a58fece9f'	System	20 Sep 2020 01:32:26
User entered 'None (1)'	System	20 Sep 2020 01:32:26

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:34:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-19T21:32:22', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'd1b0c24a-cd9b-4f89-9d94-8c9a58fece9f'	System	20 Sep 2020 01:32:26
User entered '19 Sep 2020 21:32'	System	20 Sep 2020 01:32:26

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:34:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:34:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
Data entry locked.	System	18 Sep 2020 16:23:33
User entered 'Day 3'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:34:09

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-20T21:40:24', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '49d16779-c6c0-4c67-806f-0a132a5fd79d'	System	21 Sep 2020 01:40:53
User entered 'None (1)'	System	21 Sep 2020 01:40:53

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:34:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-20T21:40:34', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '49d16779-c6c0-4c67-806f-0a132a5fd79d'	System	21 Sep 2020 01:40:53
User entered 'No (N)'	System	21 Sep 2020 01:40:53

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:34:09

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-20T21:40:39', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '49d16779-c6c0-4c67-806f-0a132a5fd79d'	System	21 Sep 2020 01:40:53
User entered 'No (N)'	System	21 Sep 2020 01:40:53

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:34:09

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-20T21:40:45', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '49d16779-c6c0-4c67-806f-0a132a5fd79d'	System	21 Sep 2020 01:40:53
User entered 'None (1)'	System	21 Sep 2020 01:40:53

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:34:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-20T21:40:50', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '49d16779-c6c0-4c67-806f-0a132a5fd79d'	System	21 Sep 2020 01:40:53
User entered '20 Sep 2020 21:40'	System	21 Sep 2020 01:40:53

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:34:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:34:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
Data entry locked.	System	18 Sep 2020 16:23:33
User entered 'Day 4'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:34:09

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-21T14:12:16', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'facbf8c2-a360-4117-9990-466e244ba3cc'	System	21 Sep 2020 18:12:32
User entered 'None (1)'	System	21 Sep 2020 18:12:32

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:34:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-21T14:12:20', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'facbf8c2-a360-4117-9990-466e244ba3cc'	System	21 Sep 2020 18:12:32
User entered 'No (N)'	System	21 Sep 2020 18:12:32

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:34:09

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-21T14:12:23', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'facbf8c2-a360-4117-9990-466e244ba3cc'	System	21 Sep 2020 18:12:32
User entered 'No (N)'	System	21 Sep 2020 18:12:32

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:34:09

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-21T14:12:27', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'facbf8c2-a360-4117-9990-466e244ba3cc'	System	21 Sep 2020 18:12:32
User entered 'None (1)'	System	21 Sep 2020 18:12:32

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:34:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-21T14:12:30', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'facbf8c2-a360-4117-9990-466e244ba3cc'	System	21 Sep 2020 18:12:32
User entered '21 Sep 2020 14:12'	System	21 Sep 2020 18:12:32

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:34:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:34:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
Data entry locked.	System	18 Sep 2020 16:23:33
User entered 'Day 5'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:34:09

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-22T13:34:15', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'e7ca4b76-fca5-4720-9599-576f725991ed'	System	22 Sep 2020 17:34:29
User entered 'None (1)'	System	22 Sep 2020 17:34:29

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:34:09

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-22T13:34:19', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'e7ca4b76-fca5-4720-9599-576f725991ed'	System	22 Sep 2020 17:34:29
User entered 'No (N)'	System	22 Sep 2020 17:34:29

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:34:09

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-22T13:34:21', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'e7ca4b76-fca5-4720-9599-576f725991ed'	System	22 Sep 2020 17:34:29
User entered 'No (N)'	System	22 Sep 2020 17:34:29

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:34:09

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-22T13:34:25', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'e7ca4b76-fca5-4720-9599-576f725991ed'	System	22 Sep 2020 17:34:29
User entered 'None (1)'	System	22 Sep 2020 17:34:29

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:34:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-22T13:34:30', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'e7ca4b76-fca5-4720-9599-576f725991ed'	System	22 Sep 2020 17:34:29
User entered '22 Sep 2020 13:34'	System	22 Sep 2020 17:34:29

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:34:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:34:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
Data entry locked.	System	18 Sep 2020 16:23:33
User entered 'Day 6'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:34:09

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-23T12:04:51', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'cee521ad-62a3-4ff3-94bb-e722a4d260ec'	System	23 Sep 2020 16:05:50
User entered 'None (1)'	System	23 Sep 2020 16:05:50

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:34:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-23T12:04:54', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'cee521ad-62a3-4ff3-94bb-e722a4d260ec'	System	23 Sep 2020 16:05:50
User entered 'No (N)'	System	23 Sep 2020 16:05:50

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:34:09

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-23T12:04:58', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'cee521ad-62a3-4ff3-94bb-e722a4d260ec'	System	23 Sep 2020 16:05:50
User entered 'No (N)'	System	23 Sep 2020 16:05:50

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:34:09

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-23T12:05:03', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'cee521ad-62a3-4ff3-94bb-e722a4d260ec'	System	23 Sep 2020 16:05:50
User entered 'None (1)'	System	23 Sep 2020 16:05:50

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:34:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-23T12:05:05', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'cee521ad-62a3-4ff3-94bb-e722a4d260ec'	System	23 Sep 2020 16:05:50
User entered '23 Sep 2020 12:05'	System	23 Sep 2020 16:05:50

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:34:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:34:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
Data entry locked.	System	18 Sep 2020 16:23:33
User entered 'Day 7'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:34:09

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-24T13:07:27', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'a48b8c7d-6441-4f47-a369-b7ebbf6d365'	System	24 Sep 2020 17:07:44
User entered 'None (1)'	System	24 Sep 2020 17:07:44

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:34:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-24T13:07:30', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'a48b8c7d-6441-4f47-a369-b7ebbf6d365'	System	24 Sep 2020 17:07:44
User entered 'No (N)'	System	24 Sep 2020 17:07:44

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:34:09

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-24T13:07:34', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'a48b8c7d-6441-4f47-a369-b7ebbf6d365'	System	24 Sep 2020 17:07:44
User entered 'No (N)'	System	24 Sep 2020 17:07:44

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:34:09

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-24T13:07:38', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'a48b8c7d-6441-4f47-a369-b7ebbf6d365'	System	24 Sep 2020 17:07:44
User entered 'None (1)'	System	24 Sep 2020 17:07:44

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:34:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-24T13:07:42', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'a48b8c7d-6441-4f47-a369-b7ebbf6d365'	System	24 Sep 2020 17:07:44
User entered '24 Sep 2020 13:07'	System	24 Sep 2020 17:07:44

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:34:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:34:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
Data entry locked.	System	18 Sep 2020 16:23:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-18T12:45:36', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '5b0b277b-574a-4473-8fcd-25dc21a5383d'	System	18 Sep 2020 16:45:59
User entered 'None (0)'	System	18 Sep 2020 16:45:59

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-18T12:45:39', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '5b0b277b-574a-4473-8fcd-25dc21a5383d'	System	18 Sep 2020 16:45:59
User entered 'None (0)'	System	18 Sep 2020 16:45:59

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-18T12:45:42', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '5b0b277b-574a-4473-8fcd-25dc21a5383d'	System	18 Sep 2020 16:45:59
User entered 'None (0)'	System	18 Sep 2020 16:45:59

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-18T12:45:45', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '5b0b277b-574a-4473-8fcd-25dc21a5383d' User entered 'None (0)'	System	18 Sep 2020 16:45:59
	System	18 Sep 2020 16:45:59

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-18T12:45:48', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '5b0b277b-574a-4473-8fcd-25dc21a5383d'	System	18 Sep 2020 16:45:59
User entered 'None (0)'	System	18 Sep 2020 16:45:59

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-18T12:45:51', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '5b0b277b-574a-4473-8fcd-25dc21a5383d'	System	18 Sep 2020 16:45:59
User entered 'None (0)'	System	18 Sep 2020 16:45:59

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-18T12:45:54', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '5b0b277b-574a-4473-8fcd-25dc21a5383d'	System	18 Sep 2020 16:45:59
User entered 'No (N)'	System	18 Sep 2020 16:45:59

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-18T12:45:59', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '5b0b277b-574a-4473-8fcd-25dc21a5383d'	System	18 Sep 2020 16:45:59
User entered '18 Sep 2020 12:45'	System	18 Sep 2020 16:45:59

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '18 Sep 2020 12:33'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:34:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '18 Sep 2020 15:03'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
Data entry locked.	System	18 Sep 2020 16:23:33
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-18T21:10:10', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'ff037bcf-d2de-4e41-827b-95dd9ceba9ae'	System	19 Sep 2020 01:10:37
User entered 'None (0)'	System	19 Sep 2020 01:10:37

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-18T21:10:12', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'ff037bcf-d2de-4e41-827b-95dd9ceba9ae'	System	19 Sep 2020 01:10:37
User entered 'None (0)'	System	19 Sep 2020 01:10:37

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-18T21:10:15', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'ff037bcf-d2de-4e41-827b-95dd9ceba9ae'	System	19 Sep 2020 01:10:37
User entered 'None (0)'	System	19 Sep 2020 01:10:37

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-18T21:10:18', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'ff037bcf-d2de-4e41-827b-95dd9ceba9ae'	System	19 Sep 2020 01:10:37
User entered 'None (0)'	System	19 Sep 2020 01:10:37

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-18T21:10:21', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'ff037bcf-d2de-4e41-827b-95dd9ceba9ae'	System	19 Sep 2020 01:10:37
User entered 'None (0)'	System	19 Sep 2020 01:10:37

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-18T21:10:24', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'ff037bcf-d2de-4e41-827b-95dd9ceba9ae'	System	19 Sep 2020 01:10:37
User entered 'None (0)'	System	19 Sep 2020 01:10:37

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-18T21:10:28', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'ff037bcf-d2de-4e41-827b-95dd9ceba9ae'	System	19 Sep 2020 01:10:37
User entered 'No (N)'	System	19 Sep 2020 01:10:37

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-18T21:10:35', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'ff037bcf-d2de-4e41-827b-95dd9ceba9ae'	System	19 Sep 2020 01:10:37
User entered '18 Sep 2020 21:10'	System	19 Sep 2020 01:10:37

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '18 Sep 2020 15:58'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:34:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
Data entry locked.	System	18 Sep 2020 16:23:33
User entered 'Day 2'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-19T21:32:28', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'f6e362c2-e2b4-4d4f-90b4-17063c207d7b'	System	20 Sep 2020 01:32:51
User entered 'None (0)'	System	20 Sep 2020 01:32:51

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-19T21:32:30', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'f6e362c2-e2b4-4d4f-90b4-17063c207d7b'	System	20 Sep 2020 01:32:51
User entered 'None (0)'	System	20 Sep 2020 01:32:51

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-19T21:32:33', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'f6e362c2-e2b4-4d4f-90b4-17063c207d7b'	System	20 Sep 2020 01:32:51
User entered 'None (0)'	System	20 Sep 2020 01:32:51

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-19T21:32:35', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'f6e362c2-e2b4-4d4f-90b4-17063c207d7b'	System	20 Sep 2020 01:32:51
User entered 'None (0)'	System	20 Sep 2020 01:32:51

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-19T21:32:38', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'f6e362c2-e2b4-4d4f-90b4-17063c207d7b'	System	20 Sep 2020 01:32:51
User entered 'None (0)'	System	20 Sep 2020 01:32:51

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-19T21:32:40', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'f6e362c2-e2b4-4d4f-90b4-17063c207d7b'	System	20 Sep 2020 01:32:51
User entered 'None (0)'	System	20 Sep 2020 01:32:51

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-19T21:32:45', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'f6e362c2-e2b4-4d4f-90b4-17063c207d7b'	System	20 Sep 2020 01:32:51
User entered 'No (N)'	System	20 Sep 2020 01:32:51

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-19T21:32:47', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'f6e362c2-e2b4-4d4f-90b4-17063c207d7b'	System	20 Sep 2020 01:32:51
User entered '19 Sep 2020 21:32'	System	20 Sep 2020 01:32:51

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:34:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
Data entry locked.	System	18 Sep 2020 16:23:33
User entered 'Day 3'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-20T21:40:56', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '4e297c5b-0100-4d1f-9abf-5bdc8ff6fb80'	System	21 Sep 2020 01:41:18
User entered 'None (0)'	System	21 Sep 2020 01:41:18

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-20T21:40:58', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '4e297c5b-0100-4d1f-9abf-5bdc8ff6fb80'	System	21 Sep 2020 01:41:18
User entered 'None (0)'	System	21 Sep 2020 01:41:18

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-20T21:41:01', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '4e297c5b-0100-4d1f-9abf-5bdc8ff6fb80'	System	21 Sep 2020 01:41:18
User entered 'None (0)'	System	21 Sep 2020 01:41:18

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-20T21:41:04', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '4e297c5b-0100-4d1f-9abf-5bdc8ff6fb80'	System	21 Sep 2020 01:41:18
User entered 'None (0)'	System	21 Sep 2020 01:41:18

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-20T21:41:07', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '4e297c5b-0100-4d1f-9abf-5bdc8ff6fb80'	System	21 Sep 2020 01:41:18
User entered 'None (0)'	System	21 Sep 2020 01:41:18

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-20T21:41:09', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '4e297c5b-0100-4d1f-9abf-5bdc8ff6fb80'	System	21 Sep 2020 01:41:18
User entered 'None (0)'	System	21 Sep 2020 01:41:18

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-20T21:41:13', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '4e297c5b-0100-4d1f-9abf-5bdc8ff6fb80'	System	21 Sep 2020 01:41:18
User entered 'No (N)'	System	21 Sep 2020 01:41:18

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-20T21:41:17', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '4e297c5b-0100-4d1f-9abf-5bdc8ff6fb80'	System	21 Sep 2020 01:41:18
User entered '20 Sep 2020 21:41'	System	21 Sep 2020 01:41:18

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:34:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
Data entry locked.	System	18 Sep 2020 16:23:33
User entered 'Day 4'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-21T14:12:35', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '10c5cee0-11f9-43fb-872d-bdf3bdc6d9c6'	System	21 Sep 2020 18:13:02
User entered 'None (0)'	System	21 Sep 2020 18:13:02

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-21T14:12:37', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '10c5cee0-11f9-43fb-872d-bdf3bdc6d9c6'	System	21 Sep 2020 18:13:02
User entered 'None (0)'	System	21 Sep 2020 18:13:02

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-21T14:12:40', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '10c5cee0-11f9-43fb-872d-bdf3bdc6d9c6'	System	21 Sep 2020 18:13:02
User entered 'None (0)'	System	21 Sep 2020 18:13:02

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-21T14:12:43', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '10c5cee0-11f9-43fb-872d-bdf3bdc6d9c6'	System	21 Sep 2020 18:13:02
User entered 'None (0)'	System	21 Sep 2020 18:13:02

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-21T14:12:45', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '10c5cee0-11f9-43fb-872d-bdf3bdc6d9c6'	System	21 Sep 2020 18:13:02
User entered 'None (0)'	System	21 Sep 2020 18:13:02

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-21T14:12:48', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '10c5cee0-11f9-43fb-872d-bdf3bdc6d9c6'	System	21 Sep 2020 18:13:02
User entered 'None (0)'	System	21 Sep 2020 18:13:02

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-21T14:12:54', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '10c5cee0-11f9-43fb-872d-bdf3bdc6d9c6'	System	21 Sep 2020 18:13:02
User entered 'No (N)'	System	21 Sep 2020 18:13:02

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-21T14:12:58', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '10c5cee0-11f9-43fb-872d-bdf3bdc6d9c6'	System	21 Sep 2020 18:13:02
User entered '21 Sep 2020 14:12'	System	21 Sep 2020 18:13:02

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:34:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
Data entry locked.	System	18 Sep 2020 16:23:33
User entered 'Day 5'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-22T13:34:34', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'e3a12216-8d60-4197-bb05-d5bc9779dc78'	System	22 Sep 2020 17:34:53
User entered 'None (0)'	System	22 Sep 2020 17:34:53

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-22T13:34:36', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'e3a12216-8d60-4197-bb05-d5bc9779dc78'	System	22 Sep 2020 17:34:53
User entered 'None (0)'	System	22 Sep 2020 17:34:53

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-22T13:34:38', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'e3a12216-8d60-4197-bb05-d5bc9779dc78'	System	22 Sep 2020 17:34:53
User entered 'None (0)'	System	22 Sep 2020 17:34:53

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-22T13:34:40', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'e3a12216-8d60-4197-bb05-d5bc9779dc78'	System	22 Sep 2020 17:34:53
User entered 'None (0)'	System	22 Sep 2020 17:34:53

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-22T13:34:42', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'e3a12216-8d60-4197-bb05-d5bc9779dc78'	System	22 Sep 2020 17:34:53
User entered 'None (0)'	System	22 Sep 2020 17:34:53

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-22T13:34:44', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'e3a12216-8d60-4197-bb05-d5bc9779dc78'	System	22 Sep 2020 17:34:53
User entered 'None (0)'	System	22 Sep 2020 17:34:53

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-22T13:34:50', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'e3a12216-8d60-4197-bb05-d5bc9779dc78'	System	22 Sep 2020 17:34:53
User entered 'No (N)'	System	22 Sep 2020 17:34:53

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-22T13:34:54', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'e3a12216-8d60-4197-bb05-d5bc9779dc78'	System	22 Sep 2020 17:34:53
User entered '22 Sep 2020 13:34'	System	22 Sep 2020 17:34:53

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:34:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
Data entry locked.	System	18 Sep 2020 16:23:33
User entered 'Day 6'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-23T12:05:11', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '06afdccb-620a-4eb4-b49e-78dc8fe58fce'	System	23 Sep 2020 16:06:00
User entered 'None (0)'	System	23 Sep 2020 16:06:00

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-23T12:05:13', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '06afdccb-620a-4eb4-b49e-78dc8fe58fce'	System	23 Sep 2020 16:06:00
User entered 'None (0)'	System	23 Sep 2020 16:06:00

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-23T12:05:15', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '06afdccb-620a-4eb4-b49e-78dc8fe58fce'	System	23 Sep 2020 16:06:00
User entered 'None (0)'	System	23 Sep 2020 16:06:00

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-23T12:05:18', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '06afdccb-620a-4eb4-b49e-78dc8fe58fce'	System	23 Sep 2020 16:06:00
User entered 'None (0)'	System	23 Sep 2020 16:06:00

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-23T12:05:19', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '06afdccb-620a-4eb4-b49e-78dc8fe58fce'	System	23 Sep 2020 16:06:00
User entered 'None (0)'	System	23 Sep 2020 16:06:00

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-23T12:05:22', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '06afdccb-620a-4eb4-b49e-78dc8fe58fce'	System	23 Sep 2020 16:06:00
User entered 'None (0)'	System	23 Sep 2020 16:06:00

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-23T12:05:25', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '06afdccb-620a-4eb4-b49e-78dc8fe58fce'	System	23 Sep 2020 16:06:00
User entered 'No (N)'	System	23 Sep 2020 16:06:00

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-23T12:05:29', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '06afdccb-620a-4eb4-b49e-78dc8fe58fce'	System	23 Sep 2020 16:06:00
User entered '23 Sep 2020 12:05'	System	23 Sep 2020 16:06:00

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:34:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
Data entry locked.	System	18 Sep 2020 16:23:33
User entered 'Day 7'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-24T13:07:47', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'bee2e258-2430-4486-99fc-38029383975d'	System	24 Sep 2020 17:08:10
User entered 'None (0)'	System	24 Sep 2020 17:08:10

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-24T13:07:49', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'bee2e258-2430-4486-99fc-38029383975d'	System	24 Sep 2020 17:08:10
User entered 'None (0)'	System	24 Sep 2020 17:08:10

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-24T13:07:52', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'bee2e258-2430-4486-99fc-38029383975d'	System	24 Sep 2020 17:08:10
User entered 'None (0)'	System	24 Sep 2020 17:08:10

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-24T13:07:55', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'bee2e258-2430-4486-99fc-38029383975d' User entered 'None (0)'	System	24 Sep 2020 17:08:10
	System	24 Sep 2020 17:08:10

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-24T13:07:57', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'bee2e258-2430-4486-99fc-38029383975d'	System	24 Sep 2020 17:08:10
User entered 'None (0)'	System	24 Sep 2020 17:08:10

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-24T13:08:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'bee2e258-2430-4486-99fc-38029383975d'	System	24 Sep 2020 17:08:10
User entered 'None (0)'	System	24 Sep 2020 17:08:10

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:09

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-24T13:08:05', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'bee2e258-2430-4486-99fc-38029383975d'	System	24 Sep 2020 17:08:10
User entered 'No (N)'	System	24 Sep 2020 17:08:10

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-09-24T13:08:08', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'bee2e258-2430-4486-99fc-38029383975d'	System	24 Sep 2020 17:08:10
User entered '24 Sep 2020 13:08'	System	24 Sep 2020 17:08:10

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 16:23:33

US3172250

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:34:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 16:23:33

US3172250

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	28 Sep 2020 18:06:15

US3172250

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:09

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '25 Sep 2020'	Jessie Downs (b) (4) (b) (4)	28 Sep 2020 18:06:15

US3172250

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	28 Sep 2020 18:06:15

US3172250

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	28 Sep 2020 18:06:15

US3172250

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	28 Sep 2020 18:06:20

US3172250

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User entered 'I'	System	28 Sep 2020 18:06:20

US3172250

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	02 Oct 2020 18:54:19

US3172250

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:09

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '2 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	02 Oct 2020 18:54:19

US3172250

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Contact Made (CONTACT MADE)'	Mariete Rendon (b) (4) (b) (4)	02 Oct 2020 18:54:19

US3172250

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	02 Oct 2020 18:54:19

US3172250

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	12 Oct 2020 14:42:43
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	08 Oct 2020 17:54:15
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	02 Oct 2020 18:54:23

US3172250

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User entered '1'	System	12 Oct 2020 14:42:43
User entered empty.	System	08 Oct 2020 17:54:15
User entered '1'	System	02 Oct 2020 18:54:23

US3172250

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	12 Oct 2020 14:43:03

US3172250

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:09

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
User entered '09 Oct 2020'	Jessie Downs (b) (4)	12 Oct 2020 14:43:03
	(b) (4)	

US3172250

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	12 Oct 2020 14:43:03

US3172250

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	12 Oct 2020 14:43:03

US3172250

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 18:23:25
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	12 Oct 2020 14:43:10

US3172250

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User entered '1'	System	27 Oct 2020 18:23:25
User entered empty.	System	12 Oct 2020 14:43:10

US3172250

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:34:09

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 18:23:35

US3172250

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:34:09

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User closed query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	03 Nov 2020 23:19:15
Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'confirmed. deviation will be documented' (Site from System).	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 18:23:50
User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	27 Oct 2020 18:23:35
User entered '27 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 18:23:35

US3172250

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:34:09

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Clinic (Clinic)'	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 18:23:35

US3172250

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:34:09

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User entered 'VISIT3'	System	27 Oct 2020 18:23:35

US3172250

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 18:24:11

US3172250

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '27 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 18:24:11

US3172250

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '08:07'	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 18:24:11

US3172250

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User entered '27 Oct 2020 08:07'	System	27 Oct 2020 18:24:11

US3172250

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '36.7' C	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 18:24:11

US3172250

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Oral (Oral)'	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 18:24:11

US3172250

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 18:24:11

US3172250

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '63'	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 18:24:11

US3172250

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User entered 'bpm'	System	27 Oct 2020 18:24:11

US3172250

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '14'	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 18:24:11

US3172250

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User entered 'breaths/min'	System	27 Oct 2020 18:24:11

US3172250

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '121'	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 18:24:11

US3172250

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User entered 'mmHg'	System	27 Oct 2020 18:24:11

US3172250

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '80'	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 18:24:11

US3172250

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User entered 'mmHg'	System	27 Oct 2020 18:24:11

US3172250

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31

US3172250

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31

US3172250

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:34:09

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 18:24:18

US3172250

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:34:09

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered empty.	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 18:24:18

US3172250

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 18:24:25

US3172250

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:09

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '27 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 18:24:25

US3172250

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:09

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '08:37'	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 18:24:25

US3172250

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:09

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User entered '27 Oct 2020 08:37'	System	27 Oct 2020 18:24:25

US3172250

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	18 Dec 2020 21:45:41
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	27 Oct 2020 18:24:36

US3172250

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User entered '1'	System	18 Dec 2020 21:45:41
User entered empty.	System	27 Oct 2020 18:24:36

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09
Data entry locked.	System	20 Aug 2020 19:44:17
User entered 'Day 64'	System	20 Aug 2020 19:44:17

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09
Data entry locked.	System	20 Aug 2020 19:44:17
User entered '20 Oct 2020 00:01'	System	20 Aug 2020 19:44:17

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09
Data entry locked.	System	20 Aug 2020 19:44:17
User entered '24 Oct 2020 23:59'	System	20 Aug 2020 19:44:17

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09
Data entry locked.	System	20 Aug 2020 19:44:17
User entered 'Day 71'	System	20 Aug 2020 19:44:17

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09
Data entry locked.	System	20 Aug 2020 19:44:17
User entered '27 Oct 2020 00:01'	System	20 Aug 2020 19:44:17

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:01:09
Data entry locked.	System	20 Aug 2020 19:44:17
User entered '31 Oct 2020 23:59'	System	20 Aug 2020 19:44:17

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
Data entry locked.	System	20 Aug 2020 19:44:17
User entered 'Day 78'	System	20 Aug 2020 19:44:17

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-11-06T15:25:01', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'cf88ceb9-45dc-431a-bf11-c113095d7071'	System	06 Nov 2020 20:25:38
User entered 'No (N)'	System	06 Nov 2020 20:25:38

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-11-06T15:25:11', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'cf88ceb9-45dc-431a-bf11-c113095d7071'	System	06 Nov 2020 20:25:38
User entered 'No (N)'	System	06 Nov 2020 20:25:38

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-11-06T15:25:33', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'cf88ceb9-45dc-431a-bf11-c113095d7071'	System	06 Nov 2020 20:25:38
User entered '06 Nov 2020 15:25:33'	System	06 Nov 2020 20:25:38

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
Data entry locked.	System	20 Aug 2020 19:44:17
User entered '03 Nov 2020 00:01'	System	20 Aug 2020 19:44:17

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
Data entry locked.	System	20 Aug 2020 19:44:17
User entered '07 Nov 2020 23:59'	System	20 Aug 2020 19:44:17

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
Data entry locked.	System	20 Aug 2020 19:44:17
User entered 'Day 92'	System	20 Aug 2020 19:44:17

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-11-17T09:16:42', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '5bcfcfa6-e07a-49fe-af1c-ca7da898ae69'	System	17 Nov 2020 14:17:02
User entered 'No (N)'	System	17 Nov 2020 14:17:02

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-11-17T09:16:49', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '5bcfcfa6-e07a-49fe-af1c-ca7da898ae69'	System	17 Nov 2020 14:17:02
User entered 'No (N)'	System	17 Nov 2020 14:17:02

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-11-17T09:17:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '5bcfcfa6-e07a-49fe-af1c-ca7da898ae69'	System	17 Nov 2020 14:17:02
User entered '17 Nov 2020 09:17:00'	System	17 Nov 2020 14:17:02

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
Data entry locked.	System	20 Aug 2020 19:44:17
User entered '17 Nov 2020 00:01'	System	20 Aug 2020 19:44:17

US3172250

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:18:39
Data entry locked.	System	20 Aug 2020 19:44:17
User entered '21 Nov 2020 23:59'	System	20 Aug 2020 19:44:17

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[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 (1a8c61b945b8e6b4)', Time: '2020-11-21T22:01:04', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '9d723841-09b6-4d6a-ac4e-9aed2fc2dd3f'	System	22 Nov 2020 03:01:21
User entered 'No (N)'	System	22 Nov 2020 03:01:21

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Have you been exposed to someone with 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 (1a8c61b945b8e6b4)', Time: '2020-11-21T21:58:42', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '9d723841-09b6-4d6a-ac4e-9aed2fc2dd3f'	System	22 Nov 2020 03:01:21
User entered 'No (N)'	System	22 Nov 2020 03:01:21

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-11-21T22:01:10', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '9d723841-09b6-4d6a-ac4e-9aed2fc2dd3f'	System	22 Nov 2020 03:01:21
User entered '21 Nov 2020 22:01:10'	System	22 Nov 2020 03:01:21

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[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 (1a8c61b945b8e6b4)', Time: '2020-11-29T11:45:08', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'baa6773b-6bc9-46bd-b329-149d5eb7c302'	System	30 Nov 2020 00:12:08
User entered 'No (N)'	System	30 Nov 2020 00:12:08

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Have you been exposed to someone with 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 (1a8c61b945b8e6b4)', Time: '2020-11-29T19:12:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'baa6773b-6bc9-46bd-b329-149d5eb7c302'	System	30 Nov 2020 00:12:08
User entered 'No (N)'	System	30 Nov 2020 00:12:08

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-11-29T19:12:07', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'baa6773b-6bc9-46bd-b329-149d5eb7c302'	System	30 Nov 2020 00:12:08
User entered '29 Nov 2020 19:12:07'	System	30 Nov 2020 00:12:08

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[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 (1a8c61b945b8e6b4)', Time: '2020-12-06T13:39:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '6d20fd60-6701-413e-ac49-a70bcfcf258d'	System	07 Dec 2020 03:34:18
User entered 'No (N)'	System	07 Dec 2020 03:34:18

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

Have you been exposed to someone with 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 (1a8c61b945b8e6b4)', Time: '2020-12-06T22:33:47', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '6d20fd60-6701-413e-ac49-a70bcfcf258d'	System	07 Dec 2020 03:34:18
User entered 'No (N)'	System	07 Dec 2020 03:34:18

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-12-06T22:34:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '6d20fd60-6701-413e-ac49-a70bcfcf258d' User entered '06 Dec 2020 22:34:00'	System	07 Dec 2020 03:34:18
	System	07 Dec 2020 03:34:18

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[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 (1a8c61b945b8e6b4)', Time: '2020-12-12T11:33:16', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '8da436f4-99e7-4f0a-84e4-c87d7536c7ee'	System	14 Dec 2020 13:52:18
User entered 'No (N)'	System	14 Dec 2020 13:52:18

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

Have you been exposed to someone with 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 (1a8c61b945b8e6b4)', Time: '2020-12-14T08:52:11', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '8da436f4-99e7-4f0a-84e4-c87d7536c7ee'	System	14 Dec 2020 13:52:18
User entered 'No (N)'	System	14 Dec 2020 13:52:18

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-12-14T08:52:20', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '8da436f4-99e7-4f0a-84e4-c87d7536c7ee' User entered '14 Dec 2020 08:52:20'	System	14 Dec 2020 13:52:18
	System	14 Dec 2020 13:52:18

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[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 (1a8c61b945b8e6b4)', Time: '2020-12-19T12:02:40', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'd570a2e6-db09-4c67-8b2b-4d17dc17b197'	System	19 Dec 2020 17:03:02
User entered 'No (N)'	System	19 Dec 2020 17:03:02

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

Have you been exposed to someone with 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 (1a8c61b945b8e6b4)', Time: '2020-12-19T12:02:49', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'd570a2e6-db09-4c67-8b2b-4d17dc17b197'	System	19 Dec 2020 17:03:02
User entered 'No (N)'	System	19 Dec 2020 17:03:02

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-12-19T12:03:01', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'd570a2e6-db09-4c67-8b2b-4d17dc17b197'	System	19 Dec 2020 17:03:02
User entered '19 Dec 2020 12:03:01'	System	19 Dec 2020 17:03:02

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[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 (1a8c61b945b8e6b4)', Time: '2020-12-26T13:40:18', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '2b2ef574-202b-423e-956d-95852bc81df4'	System	26 Dec 2020 18:40:27
User entered 'No (N)'	System	26 Dec 2020 18:40:27

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Have you been exposed to someone with 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 (1a8c61b945b8e6b4)', Time: '2020-12-26T13:40:20', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '2b2ef574-202b-423e-956d-95852bc81df4'	System	26 Dec 2020 18:40:27
User entered 'No (N)'	System	26 Dec 2020 18:40:27

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2020-12-26T13:40:23', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '2b2ef574-202b-423e-956d-95852bc81df4'	System	26 Dec 2020 18:40:27
User entered '26 Dec 2020 13:40:23'	System	26 Dec 2020 18:40:27

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[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 (1a8c61b945b8e6b4)', Time: '2021-01-02T10:22:51', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '58e757cb-9719-4335-b761-9b9bbd801f7a'	System	02 Jan 2021 15:22:59
User entered 'No (N)'	System	02 Jan 2021 15:22:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

Have you been exposed to someone with 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 (1a8c61b945b8e6b4)', Time: '2021-01-02T10:22:53', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '58e757cb-9719-4335-b761-9b9bbd801f7a'	System	02 Jan 2021 15:22:59
User entered 'No (N)'	System	02 Jan 2021 15:22:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2021-01-02T10:22:56', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '58e757cb-9719-4335-b761-9b9bbd801f7a'	System	02 Jan 2021 15:22:59
User entered '02 Jan 2021 10:22:56'	System	02 Jan 2021 15:22:59

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[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 (1a8c61b945b8e6b4)', Time: '2021-01-09T12:28:21', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'dad7944b-c6db-4eaf-9c93-bcfa15b781c2'	System	09 Jan 2021 17:28:30
User entered 'No (N)'	System	09 Jan 2021 17:28:30

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

Have you been exposed to someone with 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 (1a8c61b945b8e6b4)', Time: '2021-01-09T12:28:23', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'dad7944b-c6db-4eaf-9c93-bcfa15b781c2'	System	09 Jan 2021 17:28:30
User entered 'No (N)'	System	09 Jan 2021 17:28:30

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2021-01-09T12:28:27', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'dad7944b-c6db-4eaf-9c93-bcfa15b781c2'	System	09 Jan 2021 17:28:30
User entered '09 Jan 2021 12:28:27'	System	09 Jan 2021 17:28:30

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[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 (1a8c61b945b8e6b4)', Time: '2021-01-17T08:33:58', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '373ecec-f428-48ea-9c4d-3e2d9053544b'	System	17 Jan 2021 13:34:06
User entered 'No (N)'	System	17 Jan 2021 13:34:06

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

Have you been exposed to someone with 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 (1a8c61b945b8e6b4)', Time: '2021-01-17T08:34:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '373ecec-f428-48ea-9c4d-3e2d9053544b'	System	17 Jan 2021 13:34:06
User entered 'No (N)'	System	17 Jan 2021 13:34:06

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2021-01-17T08:34:03', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '373ecec-f428-48ea-9c4d-3e2d9053544b' User entered '17 Jan 2021 08:34:03'	System	17 Jan 2021 13:34:06

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[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 (1a8c61b945b8e6b4)', Time: '2021-01-23T18:03:55', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'f7f68e0c-d777-486a-80d8-72c73e119005'	System	23 Jan 2021 23:05:37
User entered 'Yes (Y)'	System	23 Jan 2021 23:05:37

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Have you been exposed to someone with 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 (1a8c61b945b8e6b4)', Time: '2021-01-23T18:04:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'f7f68e0c-d777-486a-80d8-72c73e119005'	System	23 Jan 2021 23:05:37
User entered 'No (N)'	System	23 Jan 2021 23:05:37

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2021-01-23T18:04:07', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'f7f68e0c-d777-486a-80d8-72c73e119005'	System	23 Jan 2021 23:05:37
User entered 'No (N)'	System	23 Jan 2021 23:05:37

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2021-01-23T18:04:16', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'f7f68e0c-d777-486a-80d8-72c73e119005'	System	23 Jan 2021 23:05:37
User entered 'No (N)'	System	23 Jan 2021 23:05:37

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2021-01-23T18:04:36', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'f7f68e0c-d777-486a-80d8-72c73e119005'	System	23 Jan 2021 23:05:37
User entered '23 Jan 2021 18:04:36'	System	23 Jan 2021 23:05:37

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[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 (1a8c61b945b8e6b4)', Time: '2021-01-31T21:13:58', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'd88c2822-9e7c-4400-8bad-3b3c4bc77127'	System	24 Feb 2021 17:43:54
User entered 'Yes (Y)'	System	24 Feb 2021 17:43:54

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

Have you been exposed to someone with 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 (1a8c61b945b8e6b4)', Time: '2021-01-31T21:14:01', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'd88c2822-9e7c-4400-8bad-3b3c4bc77127'	System	24 Feb 2021 17:43:54
User entered 'No (N)'	System	24 Feb 2021 17:43:54

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2021-01-31T21:14:07', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'd88c2822-9e7c-4400-8bad-3b3c4bc77127'	System	24 Feb 2021 17:43:54
User entered 'No (N)'	System	24 Feb 2021 17:43:54

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2021-01-31T21:14:12', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'd88c2822-9e7c-4400-8bad-3b3c4bc77127'	System	24 Feb 2021 17:43:54
User entered 'No (N)'	System	24 Feb 2021 17:43:54

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2021-01-31T21:14:18', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'd88c2822-9e7c-4400-8bad-3b3c4bc77127'	System	24 Feb 2021 17:43:54
User entered '31 Jan 2021 21:14:18'	System	24 Feb 2021 17:43:54

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[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 (1a8c61b945b8e6b4)', Time: '2021-02-06T05:16:23', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '6224ccbe-89be-4997-8ee2-1303936a84d8'	System	24 Feb 2021 17:43:56
User entered 'No (N)'	System	24 Feb 2021 17:43:56

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

Have you been exposed to someone with 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 (1a8c61b945b8e6b4)', Time: '2021-02-06T05:16:19', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '6224ccbe-89be-4997-8ee2-1303936a84d8'	System	24 Feb 2021 17:43:56
User entered 'No (N)'	System	24 Feb 2021 17:43:56

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2021-02-06T05:16:27', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '6224ccbe-89be-4997-8ee2-1303936a84d8'	System	24 Feb 2021 17:43:56
User entered '06 Feb 2021 05:16:27'	System	24 Feb 2021 17:43:56

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[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 (1a8c61b945b8e6b4)', Time: '2021-02-16T18:15:51', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '159697f3-30a7-46d5-a292-7bcb0f7a7165'	System	24 Feb 2021 17:43:57
User entered 'No (N)'	System	24 Feb 2021 17:43:57

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

Have you been exposed to someone with 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 (1a8c61b945b8e6b4)', Time: '2021-02-16T18:15:52', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '159697f3-30a7-46d5-a292-7bcb0f7a7165'	System	24 Feb 2021 17:43:57
User entered 'No (N)'	System	24 Feb 2021 17:43:57

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2021-02-16T18:15:56', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '159697f3-30a7-46d5-a292-7bcb0f7a7165' User entered '16 Feb 2021 18:15:56'	System	24 Feb 2021 17:43:57

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[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 (1a8c61b945b8e6b4)', Time: '2021-02-22T20:43:15', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '2a6b59be-90fa-4f24-b763-07db9770d8c3'	System	24 Feb 2021 17:43:58
User entered 'No (N)'	System	24 Feb 2021 17:43:58

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

Have you been exposed to someone with 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 (1a8c61b945b8e6b4)', Time: '2021-02-22T20:43:17', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '2a6b59be-90fa-4f24-b763-07db9770d8c3'	System	24 Feb 2021 17:43:58
User entered 'No (N)'	System	24 Feb 2021 17:43:58

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1a8c61b945b8e6b4)', Time: '2021-02-22T20:43:21', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '2a6b59be-90fa-4f24-b763-07db9770d8c3'	System	24 Feb 2021 17:43:58
User entered '22 Feb 2021 20:43:21'	System	24 Feb 2021 17:43:58

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[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 (c324fe68004d784c)', Time: '2021-02-27T06:02:58-05:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'dc5ba508-fef9-4bb4-89b0-6c17ef1e6659' User entered 'No (N)'	System	27 Feb 2021 11:03:09
	System	27 Feb 2021 11:03:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

Have you been exposed to someone with 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 (c324fe68004d784c)', Time: '2021-02-27T06:03:00-05:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'dc5ba508-fef9-4bb4-89b0-6c17ef1e6659'	System	27 Feb 2021 11:03:09
User entered 'No (N)'	System	27 Feb 2021 11:03:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c324fe68004d784c)', Time: '2021-02-27T06:03:04-05:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'dc5ba508-fef9-4bb4-89b0-6c17ef1e6659' User entered '27 Feb 2021 06:03:04'	System	27 Feb 2021 11:03:09
	System	27 Feb 2021 11:03:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[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 (c324fe68004d784c)', Time: '2021-03-06T02:52:05-05:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'de034df7-59b2-4ab0-b065-49a6012925b6'	System	06 Mar 2021 07:54:31
User entered 'Yes (Y)'	System	06 Mar 2021 07:54:31

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

Have you been exposed to someone with 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 (c324fe68004d784c)', Time: '2021-03-06T02:52:29-05:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'de034df7-59b2-4ab0-b065-49a6012925b6'	System	06 Mar 2021 07:54:31
User entered 'Yes (Y)'	System	06 Mar 2021 07:54:31

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c324fe68004d784c)', Time: '2021-03-06T02:52:46-05:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'de034df7-59b2-4ab0-b065-49a6012925b6'	System	06 Mar 2021 07:54:31
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Mar 2021 07:54:31

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c324fe68004d784c)', Time: '2021-03-06T02:53:01-05:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'de034df7-59b2-4ab0-b065-49a6012925b6'	System	06 Mar 2021 07:54:31
User entered 'Yes (Y)'	System	06 Mar 2021 07:54:31

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c324fe68004d784c)', Time: '2021-03-06T02:53:44-05:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'de034df7-59b2-4ab0-b065-49a6012925b6'	System	06 Mar 2021 07:54:31
User entered '0'	System	06 Mar 2021 07:54:31

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c324fe68004d784c)', Time: '2021-03-06T02:53:44-05:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'de034df7-59b2-4ab0-b065-49a6012925b6'	System	06 Mar 2021 07:54:31
User entered '0'	System	06 Mar 2021 07:54:31

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c324fe68004d784c)', Time: '2021-03-06T02:53:44-05:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'de034df7-59b2-4ab0-b065-49a6012925b6'	System	06 Mar 2021 07:54:31
User entered '0'	System	06 Mar 2021 07:54:31

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c324fe68004d784c)', Time: '2021-03-06T02:53:44-05:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'de034df7-59b2-4ab0-b065-49a6012925b6'	System	06 Mar 2021 07:54:31
User entered '0'	System	06 Mar 2021 07:54:31

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c324fe68004d784c)', Time: '2021-03-06T02:53:44-05:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'de034df7-59b2-4ab0-b065-49a6012925b6'	System	06 Mar 2021 07:54:31
User entered '0'	System	06 Mar 2021 07:54:31

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c324fe68004d784c)', Time: '2021-03-06T02:53:44-05:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'de034df7-59b2-4ab0-b065-49a6012925b6'	System	06 Mar 2021 07:54:31
User entered '0'	System	06 Mar 2021 07:54:31

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c324fe68004d784c)', Time: '2021-03-06T02:53:44-05:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'de034df7-59b2-4ab0-b065-49a6012925b6'	System	06 Mar 2021 07:54:31
User entered '1'	System	06 Mar 2021 07:54:31

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c324fe68004d784c)', Time: '2021-03-06T02:53:44-05:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'de034df7-59b2-4ab0-b065-49a6012925b6'	System	06 Mar 2021 07:54:31
User entered '0'	System	06 Mar 2021 07:54:31

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c324fe68004d784c)', Time: '2021-03-06T02:53:44-05:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'de034df7-59b2-4ab0-b065-49a6012925b6'	System	06 Mar 2021 07:54:31
User entered '0'	System	06 Mar 2021 07:54:31

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c324fe68004d784c)', Time: '2021-03-06T02:53:44-05:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'de034df7-59b2-4ab0-b065-49a6012925b6'	System	06 Mar 2021 07:54:31
User entered '0'	System	06 Mar 2021 07:54:31

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c324fe68004d784c)', Time: '2021-03-06T02:53:44-05:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'de034df7-59b2-4ab0-b065-49a6012925b6'	System	06 Mar 2021 07:54:31
User entered '0'	System	06 Mar 2021 07:54:31

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c324fe68004d784c)', Time: '2021-03-06T02:53:44-05:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'de034df7-59b2-4ab0-b065-49a6012925b6'	System	06 Mar 2021 07:54:31
User entered '0'	System	06 Mar 2021 07:54:31

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c324fe68004d784c)', Time: '2021-03-06T02:53:44-05:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'de034df7-59b2-4ab0-b065-49a6012925b6'	System	06 Mar 2021 07:54:31
User entered '0'	System	06 Mar 2021 07:54:31

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c324fe68004d784c)', Time: '2021-03-06T02:53:44-05:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'de034df7-59b2-4ab0-b065-49a6012925b6'	System	06 Mar 2021 07:54:31
User entered '0'	System	06 Mar 2021 07:54:31

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c324fe68004d784c)', Time: '2021-03-06T02:53:44-05:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'de034df7-59b2-4ab0-b065-49a6012925b6'	System	06 Mar 2021 07:54:31
User entered '0'	System	06 Mar 2021 07:54:31

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c324fe68004d784c)', Time: '2021-03-06T02:53:44-05:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'de034df7-59b2-4ab0-b065-49a6012925b6'	System	06 Mar 2021 07:54:31
User entered '0'	System	06 Mar 2021 07:54:31

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c324fe68004d784c)', Time: '2021-03-06T02:53:44-05:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'de034df7-59b2-4ab0-b065-49a6012925b6'	System	06 Mar 2021 07:54:31
User entered '0'	System	06 Mar 2021 07:54:31

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c324fe68004d784c)', Time: '2021-03-06T02:53:57-05:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'de034df7-59b2-4ab0-b065-49a6012925b6'	System	06 Mar 2021 07:54:31
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Mar 2021 07:54:31

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c324fe68004d784c)', Time: '2021-03-06T02:54:07-05:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'de034df7-59b2-4ab0-b065-49a6012925b6'	System	06 Mar 2021 07:54:31
User entered 'Yes (Y)'	System	06 Mar 2021 07:54:31

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c324fe68004d784c)', Time: '2021-03-06T02:54:10-05:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'de034df7-59b2-4ab0-b065-49a6012925b6'	System	06 Mar 2021 07:54:31
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Mar 2021 07:54:31

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c324fe68004d784c)', Time: '2021-03-06T02:54:19-05:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'de034df7-59b2-4ab0-b065-49a6012925b6'	System	06 Mar 2021 07:54:31
User entered '06 Mar 2021 02:54:19'	System	06 Mar 2021 07:54:31

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[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 (c324fe68004d784c)', Time: '2021-03-13T11:59:23-05:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '32cb73aa-2b96-4206-9bf2-267a2b586c3e'	System	13 Mar 2021 16:59:51
User entered 'Yes (Y)'	System	13 Mar 2021 16:59:51

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

Have you been exposed to someone with 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 (c324fe68004d784c)', Time: '2021-03-13T11:59:28-05:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '32cb73aa-2b96-4206-9bf2-267a2b586c3e'	System	13 Mar 2021 16:59:51
User entered 'No (N)'	System	13 Mar 2021 16:59:51

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c324fe68004d784c)', Time: '2021-03-13T11:59:32-05:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '32cb73aa-2b96-4206-9bf2-267a2b586c3e'	System	13 Mar 2021 16:59:51
User entered 'No (N)'	System	13 Mar 2021 16:59:51

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c324fe68004d784c)', Time: '2021-03-13T11:59:42-05:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '32cb73aa-2b96-4206-9bf2-267a2b586c3e'	System	13 Mar 2021 16:59:51
User entered 'No (N)'	System	13 Mar 2021 16:59:51

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c324fe68004d784c)', Time: '2021-03-13T11:59:46-05:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '32cb73aa-2b96-4206-9bf2-267a2b586c3e'	System	13 Mar 2021 16:59:51
User entered '13 Mar 2021 11:59:46'	System	13 Mar 2021 16:59:51

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[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 (c324fe68004d784c)', Time: '2021-03-20T18:36:17-04:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'a7f1ab6b-36bb-4ddc-8685-ef6461a62d20'	System	20 Mar 2021 22:36:37
User entered 'No (N)'	System	20 Mar 2021 22:36:37

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

Have you been exposed to someone with 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 (c324fe68004d784c)', Time: '2021-03-20T18:36:20-04:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'a7f1ab6b-36bb-4ddc-8685-ef6461a62d20'	System	20 Mar 2021 22:36:37
User entered 'No (N)'	System	20 Mar 2021 22:36:37

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c324fe68004d784c)', Time: '2021-03-20T18:36:30-04:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'a7f1ab6b-36bb-4ddc-8685-ef6461a62d20'	System	20 Mar 2021 22:36:37
User entered '20 Mar 2021 18:36:30'	System	20 Mar 2021 22:36:37

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[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 (c324fe68004d784c)', Time: '2021-03-27T21:50:31-04:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '68043b6a-0f30-4720-8a35-7624398dcae7'	System	28 Mar 2021 01:50:54
User entered 'No (N)'	System	28 Mar 2021 01:50:54

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

Have you been exposed to someone with 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 (c324fe68004d784c)', Time: '2021-03-27T21:50:36-04:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '68043b6a-0f30-4720-8a35-7624398dcae7'	System	28 Mar 2021 01:50:54
User entered 'No (N)'	System	28 Mar 2021 01:50:54

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c324fe68004d784c)', Time: '2021-03-27T21:50:48-04:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '68043b6a-0f30-4720-8a35-7624398dcae7' User entered '27 Mar 2021 21:50:48'	System	28 Mar 2021 01:50:54
	System	28 Mar 2021 01:50:54

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[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 (c324fe68004d784c)', Time: '2021-04-03T08:41:43-04:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'dad65820-ccdc-4d24-baff-7f1aac1c8938'	System	03 Apr 2021 12:41:57
User entered 'No (N)'	System	03 Apr 2021 12:41:57

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

Have you been exposed to someone with 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 (c324fe68004d784c)', Time: '2021-04-03T08:41:46-04:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'dad65820-ccdc-4d24-baff-7f1aac1c8938'	System	03 Apr 2021 12:41:57
User entered 'No (N)'	System	03 Apr 2021 12:41:57

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c324fe68004d784c)', Time: '2021-04-03T08:41:51-04:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'dad65820-ccdc-4d24-baff-7f1aac1c8938'	System	03 Apr 2021 12:41:57
User entered '03 Apr 2021 08:41:51'	System	03 Apr 2021 12:41:57

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[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 (c324fe68004d784c)', Time: '2021-04-11T13:01:50-04:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '4b4fb968-31a8-4f8c-b495-e368d87be803'	System	11 Apr 2021 17:04:01
User entered 'No (N)'	System	11 Apr 2021 17:04:01

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

Have you been exposed to someone with 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 (c324fe68004d784c)', Time: '2021-04-11T13:01:53-04:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '4b4fb968-31a8-4f8c-b495-e368d87be803'	System	11 Apr 2021 17:04:01
User entered 'No (N)'	System	11 Apr 2021 17:04:01

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c324fe68004d784c)', Time: '2021-04-11T13:02:01-04:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '4b4fb968-31a8-4f8c-b495-e368d87be803'	System	11 Apr 2021 17:04:01
User entered '11 Apr 2021 13:02:01'	System	11 Apr 2021 17:04:01

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[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 (2c935d740abb1ae2)', Time: '2021-04-19T10:45:20-04:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'dcfc3660-61c3-4dc9-86b2-6e3ef5a1debf'	System	19 Apr 2021 14:45:33
User entered 'No (N)'	System	19 Apr 2021 14:45:33

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

Have you been exposed to someone with 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 (2c935d740abb1ae2)', Time: '2021-04-19T10:45:22-04:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'dcfc3660-61c3-4dc9-86b2-6e3ef5a1debf'	System	19 Apr 2021 14:45:33
User entered 'No (N)'	System	19 Apr 2021 14:45:33

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2c935d740abb1ae2)', Time: '2021-04-19T10:45:25-04:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'dcfc3660-61c3-4dc9-86b2-6e3ef5a1debf'	System	19 Apr 2021 14:45:33
User entered '19 Apr 2021 10:45:25'	System	19 Apr 2021 14:45:33

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[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 (2c935d740abb1ae2)', Time: '2021-04-24T12:00:08-04:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '38003534-a5e3-4101-8dc8-b88b7e078a46'	System	24 Apr 2021 16:00:49
User entered 'No (N)'	System	24 Apr 2021 16:00:49

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

Have you been exposed to someone with 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 (2c935d740abb1ae2)', Time: '2021-04-24T12:00:19-04:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '38003534-a5e3-4101-8dc8-b88b7e078a46'	System	24 Apr 2021 16:00:49
User entered 'No (N)'	System	24 Apr 2021 16:00:49

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2c935d740abb1ae2)', Time: '2021-04-24T12:00:28-04:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '38003534-a5e3-4101-8dc8-b88b7e078a46'	System	24 Apr 2021 16:00:49
User entered '24 Apr 2021 12:00:28'	System	24 Apr 2021 16:00:49

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[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 (2c935d740abb1ae2)', Time: '2021-05-01T00:03:30-04:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'bbff7e0e-eca8-4970-b2f9-80144c56484d'	System	01 May 2021 04:56:44
User entered 'No (N)'	System	01 May 2021 04:56:44

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

Have you been exposed to someone with 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 (2c935d740abb1ae2)', Time: '2021-05-01T00:03:31-04:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'bbff7e0e-eca8-4970-b2f9-80144c56484d'	System	01 May 2021 04:56:44
User entered 'No (N)'	System	01 May 2021 04:56:44

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2c935d740abb1ae2)', Time: '2021-05-01T00:03:40-04:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: 'bbff7e0e-eca8-4970-b2f9-80144c56484d'	System	01 May 2021 04:56:44
User entered '01 May 2021 00:03:40'	System	01 May 2021 04:56:44

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 00:01:09

US3172250

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:34:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:01:09
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 00:01:09

US3172250

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:34:09

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c324fe68004d784c)', Time: '2021-03-13T12:00:00-05:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '4ec61ba6-9613-4598-bdf7-8bc12c5cf877'	System	13 Mar 2021 17:00:09
User entered 'No (N)'	System	13 Mar 2021 17:00:09

US3172250

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:34:09

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:34:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c324fe68004d784c)', Time: '2021-03-13T12:00:04-05:00', User OID: 'PatientReportedOutcome (US3172250)', ODM File OID: '4ec61ba6-9613-4598-bdf7-8bc12c5cf877'	System	13 Mar 2021 17:00:09
User entered '13 Mar 2021 12:00:04'	System	13 Mar 2021 17:00:09

US3172250

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	18 Dec 2020 21:46:57

US3172250

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:09

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
User entered '13 Nov 2020'	Jessie Downs (b) (4)	18 Dec 2020 21:46:57
	(b) (4)	

US3172250

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	18 Dec 2020 21:46:57

US3172250

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Dec 2020 21:46:57

US3172250

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	18 Dec 2020 21:45:56

US3172250

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:12:31
User entered 'I'	System	18 Dec 2020 21:45:56

US3172250

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:06:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	18 Dec 2020 21:46:29

US3172250

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:09

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:06:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '18 Dec 2020'	Jessie Downs (b) (4) (b) (4)	18 Dec 2020 21:46:29

US3172250

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:06:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	18 Dec 2020 21:46:29

US3172250

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:06:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Dec 2020 21:46:29

US3172250

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:06:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	18 Dec 2020 21:47:04

US3172250

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:06:11
User entered 'I'	System	18 Dec 2020 21:47:04

US3172250

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:06:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	18 Jan 2021 22:29:27

US3172250

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:09

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:06:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '18 Jan 2021'	Jessie Downs (b) (4) (b) (4)	18 Jan 2021 22:29:27

US3172250

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:06:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	18 Jan 2021 22:29:27

US3172250

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:06:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Jan 2021 22:29:27

US3172250

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:06:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	18 Jan 2021 22:29:35

US3172250

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:06:11
User entered 'I'	System	18 Jan 2021 22:29:35

US3172250

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:06:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:37:26
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	18 Feb 2021 20:48:24

US3172250

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:09

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:06:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:37:26
User entered '18 Feb 2021'	Jessie Downs (b) (4) (b) (4)	18 Feb 2021 20:48:24

US3172250

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:06:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:37:26
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	18 Feb 2021 20:48:24

US3172250

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:06:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:37:26
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Feb 2021 20:48:24

US3172250

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:06:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:37:26
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	18 Feb 2021 20:48:54

US3172250

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:06:11
User entered 'I'	System	18 Feb 2021 20:48:54

US3172250

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:34:09

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 21:32:08

US3172250

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:34:09

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered '24 Mar 2021'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 21:32:08

US3172250

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:34:09

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered 'Clinic (Clinic)'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 21:32:08

US3172250

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:34:09

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:07
User entered 'VISIT4'	System	30 Mar 2021 21:32:08

US3172250

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 21:33:10

US3172250

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered '24 Mar 2021'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 21:33:10

US3172250

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered '10:15'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 21:33:10

US3172250

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:07
User entered '24 Mar 2021 10:15'	System	30 Mar 2021 21:33:10

US3172250

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered '36.5' C	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 21:33:10

US3172250

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 21:33:10

US3172250

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 21:33:10

US3172250

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered '66'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 21:33:10

US3172250

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:07
User entered 'bpm'	System	30 Mar 2021 21:33:10

US3172250

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User closed query 'Data is required. Please provide.' (Site from System).	System	31 Mar 2021 14:52:27
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	31 Mar 2021 14:52:27
User entered '17' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	31 Mar 2021 14:52:27
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Mar 2021 21:33:10
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 21:33:10

US3172250

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:07
User entered 'breaths/min'	System	31 Mar 2021 14:52:27
User entered empty.	System	30 Mar 2021 21:33:10

US3172250

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered '131'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 21:33:10

US3172250

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:07
User entered 'mmHg'	System	30 Mar 2021 21:33:10

US3172250

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered '84'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 21:33:10

US3172250

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:07
User entered 'mmHg'	System	30 Mar 2021 21:33:10

US3172250

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:07

US3172250

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:34:09

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:07

US3172250

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:34:09

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 21:33:32

US3172250

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:34:09

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered '24 Mar 2021'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 21:33:32

US3172250

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 21:33:49

US3172250

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:09

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered '24 Mar 2021'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 21:33:49

US3172250

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:09

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered '13:36'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 21:33:49

US3172250

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:09

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered '24 Mar 2021 13:36'	System	30 Mar 2021 21:33:49

US3172250

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 21:33:52

US3172250

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:18:06
User entered 'I'	System	30 Mar 2021 21:33:52

US3172250

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	19 Apr 2021 18:44:48
Query 'Data is required. Please complete.' answered with 'added in error' (Site from System).	Jessie Downs (b) (4)	16 Apr 2021 20:03:04
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 20:02:48
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4)	16 Apr 2021 20:02:48
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	16 Apr 2021 20:02:28
	(b) (4)	

US3172250

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:09

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 20:02:48
User entered '16 Apr 2021'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 20:02:28

US3172250

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 20:02:48
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 20:02:28

US3172250

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 20:02:28

US3172250

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	19 Apr 2021 17:42:30
Query 'Data is required. Please complete.' answered with 'added in error' (Site from System).	Jessie Downs (b) (4)	16 Apr 2021 20:03:18
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	16 Apr 2021 20:02:53
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4)	16 Apr 2021 20:02:53
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	16 Apr 2021 20:02:33
	(b) (4)	

US3172250

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:09

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 20:02:53
User entered '1'	System	16 Apr 2021 20:02:33

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:34:09

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:55:57
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 18:30:57

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:34:09

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:55:57
User entered '24 Feb 2021'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 18:30:57

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:34:09

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:55:57
User entered 'Clinic (Clinic)'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 18:30:57

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:34:09

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User entered 'UNBLND_DECIDE'	System	25 Feb 2021 18:30:57

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:34:09

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:55:57
	(b) (4)	
User entered '06 Jan 2021'	Jessie Downs (b) (4)	25 Feb 2021 18:32:06
	(b) (4)	

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:34:09

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User signature succeeded.	Mark Kutner (b) (4)	12 Mar 2021 20:14:42
	(b) (4)	
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:11:38

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:34:09

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:55:57
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 18:32:06

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:34:09

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User closed query ' Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.	(b) (4), (b) (6)	15 Apr 2021 20:13:20
' (Site from DM). Query ' Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 14:02:29
' answered with 'Data was updated.' (Site from DM). Signature has been broken.	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 14:02:10
User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 14:02:10
User opened query ' Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.	(b) (4), (b) (6)	09 Apr 2021 21:46:56
' (Site from DM). User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:14:42
User entered empty. WR# 5295537 Amendment Manager inserted this DataPoint.	System System	10 Mar 2021 16:55:28 06 Mar 2021 17:11:38

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:34:09

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:55:57
User entered '24 Feb 2021'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 18:32:06

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:34:09

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:55:57
User entered 'Placebo (Placebo)'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 18:32:06

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:34:09

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:55:57
User entered 'Placebo (Placebo)'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 18:32:06

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:34:09

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:55:57
User entered 'Placebo (Placebo)'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 18:32:06

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:34:09

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:55:57
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 18:32:06

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:34:09

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User entered '1'	System	25 Feb 2021 18:32:06

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:34:09

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User entered 'I'	System	25 Feb 2021 18:32:06

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:34:09

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:55:57
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 18:34:29

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:34:09

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:41:57
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	04 Mar 2021 20:22:59
User entered '110.6' kg reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	04 Mar 2021 20:22:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:55:57
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 18:34:29

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:34:09

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User entered empty.	System	25 Feb 2021 18:34:29
DataPoint set to visible.	System	25 Feb 2021 18:32:06

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:34:09

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:55:57
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 18:34:29

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:34:09

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:41:57
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	04 Mar 2021 20:22:59
User entered '110.6' kg reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	04 Mar 2021 20:22:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:55:57
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 18:34:29

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:34:09

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User entered empty.	System	25 Feb 2021 18:34:29
DataPoint set to visible.	System	25 Feb 2021 18:32:06

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User accepted default value 'Pre-Dose (PREDOSE)'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 18:34:29

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:55:57
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 18:34:29

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:55:57
User entered '24 Feb 2021'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 18:34:29

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:55:57
User entered '12:52'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 18:34:29

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User entered '24 Feb 2021 12:52'	System	25 Feb 2021 18:34:29

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:55:57
User entered '36.9' C	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 18:34:29

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:55:57
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 18:34:29

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:55:57
User entered empty.	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 18:34:29

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:55:57
User entered '60'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 18:34:29

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User entered 'bpm'	System	25 Feb 2021 18:34:29

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:55:57
User entered '14'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 18:34:29

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User entered 'breaths/min'	System	25 Feb 2021 18:34:29

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:55:57
User entered '100'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 18:34:29

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User entered 'mmHg'	System	25 Feb 2021 18:34:29

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:55:57
User entered '66'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 18:34:29

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User entered 'mmHg'	System	25 Feb 2021 18:34:29

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:34:09

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:55:57
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 18:34:29

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:34:09

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:41:57
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	04 Mar 2021 20:22:59
User entered '110.6' kg reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	04 Mar 2021 20:22:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:55:57
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 18:34:29

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:34:09

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User entered empty.	System	25 Feb 2021 18:34:29
DataPoint set to visible.	System	25 Feb 2021 18:32:06

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User accepted default value 'Post-Dose (POSTDOSE)'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 18:34:29

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:55:57
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 18:34:29

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:55:57
User entered '24 Feb 2021'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 18:34:29

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:55:57
	(b) (4)	
User entered '15:52'	Jessie Downs (b) (4)	25 Feb 2021 18:34:29
	(b) (4)	

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User entered '24 Feb 2021 15:52'	System	25 Feb 2021 18:34:29

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:55:57
User entered '36.7' C	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 18:34:29

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:55:57
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 18:34:29

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:55:57
User entered empty.	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 18:34:29

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:55:57
User entered '65'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 18:34:29

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User entered 'bpm'	System	25 Feb 2021 18:34:29

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:55:57
User entered '17'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 18:34:29

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User entered 'breaths/min'	System	25 Feb 2021 18:34:29

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:55:57
User entered '112'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 18:34:29

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User entered 'mmHg'	System	25 Feb 2021 18:34:29

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:55:57
User entered '77'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 18:34:29

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User entered 'mmHg'	System	25 Feb 2021 18:34:29

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:34:09

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:55:57
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 18:32:21

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:34:09

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:55:57
User entered '24 Feb 2021'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 18:32:21

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:34:09

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:55:57
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 18:32:51

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:34:09

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:55:57
User entered empty.	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 18:32:51

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:34:09

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:55:57
User entered empty.	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 18:32:51

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:34:09

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User entered 'mRNA-1273'	System	25 Feb 2021 18:32:51
DataPoint set to visible.	System	25 Feb 2021 18:32:06

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:34:09

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:55:57
User entered '24 Feb 2021'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 18:32:51

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:34:09

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:55:57
User entered '15:22'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 18:32:51

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:34:09

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User entered '24 Feb 2021 15:22'	System	25 Feb 2021 18:32:51

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:34:09

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:55:57
User entered 'Left Arm (LEFT ARM)'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 18:32:51

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:34:09

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User entered 'ONCE'	System	25 Feb 2021 18:32:51

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:34:09

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User entered 'INTRAMUSCULAR'	System	25 Feb 2021 18:32:51

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:55:57
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 18:31:30

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:09

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:55:57
User entered '24 Feb 2021'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 18:31:30

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:09

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:55:57
	(b) (4)	
User entered '15:04'	Jessie Downs (b) (4)	25 Feb 2021 18:31:30
	(b) (4)	

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:34:09

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User entered '24 Feb 2021 15:04'	System	25 Feb 2021 18:31:30

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:34:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:55:57
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 18:31:44

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:34:09

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:55:57
User entered '24 Feb 2021'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 18:31:44

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:34:09

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:55:57
User entered '15:05'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 18:31:44

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:34:09

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User entered '24 Feb 2021 15:05'	System	25 Feb 2021 18:31:44

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:55:57
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 18:32:12

US3172250

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:05
User entered 'I'	System	25 Feb 2021 18:32:12

US3172250

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:42:34
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	31 Mar 2021 14:48:25
	(b) (4)	

US3172250

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:09

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:42:34
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	31 Mar 2021 14:48:25
	(b) (4)	

US3172250

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:42:34
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	31 Mar 2021 14:48:25
	(b) (4)	

US3172250

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:34:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:42:34
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'missed'	Jessie Downs (b) (4)	31 Mar 2021 14:48:25
	(b) (4)	

US3172250

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:42:34
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	30 Mar 2021 21:34:30
	(b) (4)	

US3172250

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:42:34
User entered 'I'	System	30 Mar 2021 21:34:30

US3172250

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:09

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:42:34
User entered 'I'	System	30 Mar 2021 21:34:30
DataPoint set to visible.	System	30 Mar 2021 21:34:30

US3172250

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:34:09

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 21:34:44

US3172250

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:34:09

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered '24 Mar 2021'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 21:34:44

US3172250

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:34:09

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered 'Clinic (Clinic)'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 21:34:44

US3172250

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:34:09

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User entered 'OLD29'	System	30 Mar 2021 21:34:44

US3172250

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User accepted default value 'Pre-Dose (PREDOSE)'	Jessie Downs (b) (4)	30 Mar 2021 21:36:31
	(b) (4)	

US3172250

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 21:36:31

US3172250

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '24 Mar 2021'	Jessie Downs (b) (4)	30 Mar 2021 21:36:31
	(b) (4)	

US3172250

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '10:15'	Jessie Downs (b) (4)	30 Mar 2021 21:36:31
	(b) (4)	

US3172250

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User entered '24 Mar 2021 10:15'	System	30 Mar 2021 21:36:31

US3172250

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered '36.5' C	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 21:36:31

US3172250

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 21:36:31

US3172250

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 21:36:31

US3172250

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered '66'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 21:36:31

US3172250

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User entered 'bpm'	System	30 Mar 2021 21:36:31

US3172250

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered '17'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 21:36:31

US3172250

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User entered 'breaths/min'	System	30 Mar 2021 21:36:31

US3172250

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered '131'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 21:36:31

US3172250

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User entered 'mmHg'	System	30 Mar 2021 21:36:31

US3172250

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered '84'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 21:36:31

US3172250

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:34:09

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User entered 'mmHg'	System	30 Mar 2021 21:36:31

US3172250

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User accepted default value 'Post-Dose (POSTDOSE)'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 21:36:31

US3172250

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 21:36:31

US3172250

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '24 Mar 2021'	Jessie Downs (b) (4)	30 Mar 2021 21:36:31
	(b) (4)	

US3172250

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered '14:30'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 21:36:31

US3172250

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User entered '24 Mar 2021 14:30'	System	30 Mar 2021 21:36:31

US3172250

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered '36.6' C	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 21:36:31

US3172250

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 21:36:31

US3172250

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 21:36:31

US3172250

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered '68'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 21:36:31

US3172250

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User entered 'bpm'	System	30 Mar 2021 21:36:31

US3172250

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered '16'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 21:36:31

US3172250

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User entered 'breaths/min'	System	30 Mar 2021 21:36:31

US3172250

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered '135'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 21:36:31

US3172250

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User entered 'mmHg'	System	30 Mar 2021 21:36:31

US3172250

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered '90'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 21:36:31

US3172250

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:34:09

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User entered 'mmHg'	System	30 Mar 2021 21:36:31

US3172250

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:34:09

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 21:35:35

US3172250

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:34:09

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '24 Mar 2021'	Jessie Downs (b) (4)	30 Mar 2021 21:35:35
	(b) (4)	

US3172250

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:34:09

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 21:35:11

US3172250

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:34:09

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 21:35:11

US3172250

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:34:09

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)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	30 Mar 2021 21:35:11
	(b) (4)	

US3172250

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:34:09

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User entered 'mRNA-1273'	System	30 Mar 2021 21:35:11
DataPoint set to visible.	System	30 Mar 2021 21:34:30

US3172250

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:34:09

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered '24 Mar 2021'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 21:35:11

US3172250

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:34:09

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered '14:00'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 21:35:11

US3172250

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:34:09

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User entered '24 Mar 2021 14:00'	System	30 Mar 2021 21:35:11

US3172250

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:34:09

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered 'Left Arm (LEFT ARM)'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 21:35:11

US3172250

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:34:09

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User entered 'ONCE'	System	30 Mar 2021 21:35:11

US3172250

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:34:09

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User entered 'INTRAMUSCULAR'	System	30 Mar 2021 21:35:11

US3172250

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 21:35:21

US3172250

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:34:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:11
User entered 'I'	System	30 Mar 2021 21:35:21

US3172250

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:34:09

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:07:08
User closed query 'Per DM CLR: Per Day 201 on Safety Follow-up Diary, Experienced any new COVID-19 symptoms since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM). Query 'Per DM CLR: Per Day 201 on Safety Follow-up Diary, Experienced any new COVID-19 symptoms since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' answered with 'Subject added in error.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 06:16:06
User opened query 'Per DM CLR: Per Day 201 on Safety Follow-up Diary, Experienced any new COVID-19 symptoms since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	Jessie Downs (b) (4) (b) (4)	29 Mar 2021 17:31:58
User signature succeeded.	(b) (4), (b) (6)	26 Mar 2021 02:19:34
User entered 'Yes (Y)' reason for change: Data Entry Error	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 15:30:36
	Mariete Rendon (b) (4) (b) (4)	16 Sep 2020 14:13:12

US3172250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:09

[AEID](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:54:40
DataPoint inactivated with code reason code Data not required.	Mariete Rendon (b) (4) (b) (4)	12 Nov 2020 19:28:13

US3172250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:09

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:35:11
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia, LLT: Anemia - version MedDRA\\23.0.	Coder Import (b) (4)	05 Apr 2021 20:57:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	05 Apr 2021 20:57:43
Data point term sent to Coder	System	05 Apr 2021 20:56:18
Coding entries removed.	Jessie Downs (b) (4)	05 Apr 2021 20:55:34
User entered 'anemia' reason for change: Data Entry Error	(b) (4)	05 Apr 2021 20:55:34
Data point term sent to Coder	System	05 Apr 2021 20:55:17
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	05 Apr 2021 20:54:40
Data point term sent to Coder	(b) (4)	12 Nov 2020 19:29:03
DataPoint inactivated with code reason code Data not required.	System	12 Nov 2020 19:28:13
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema peripheral, LLT: Edema of lower extremities - version MedDRA\\23.0.	Mariete Rendon (b) (4)	21 Sep 2020 15:33:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 15:33:39
Data point term sent to Coder	(b) (4)	21 Sep 2020 15:32:36
User entered 'bilateral lower extremities edema'	System	21 Sep 2020 15:32:08
	Mariete Rendon (b) (4)	
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:09

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:35:11
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	05 Apr 2021 20:55:34
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	05 Apr 2021 20:54:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Mariete Rendon (b) (4)	12 Nov 2020 19:28:13
User entered 'Yes (Y)'	(b) (4)	
	Mariete Rendon (b) (4)	21 Sep 2020 15:32:08
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:09

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:35:11
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:54:40
DataPoint inactivated with code reason code Data not required.	Mariete Rendon (b) (4) (b) (4)	12 Nov 2020 19:28:13
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 15:32:08

US3172250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:35:11
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:54:40
DataPoint inactivated with code reason code Data not required.	Mariete Rendon (b) (4) (b) (4)	12 Nov 2020 19:28:13
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 15:32:08

US3172250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:35:11
User entered '16 Sep 2020' reason for change: Data Entry Error	Jessie Downs (b) (4)	05 Apr 2021 20:55:34
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	05 Apr 2021 20:54:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Mariete Rendon (b) (4)	12 Nov 2020 19:28:13
User entered '12 Sep 2020'	(b) (4)	
	Mariete Rendon (b) (4)	21 Sep 2020 15:32:08
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:09

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:35:11
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	05 Apr 2021 20:54:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Mariete Rendon (b) (4)	12 Nov 2020 19:28:13
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	21 Sep 2020 15:32:08
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:09

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:54:40
DataPoint inactivated with code reason code Data not required.	Mariete Rendon (b) (4) (b) (4)	12 Nov 2020 19:28:13
User entered empty.	System	21 Sep 2020 15:32:08

US3172250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:35:11
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4)	05 Apr 2021 20:55:34
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	05 Apr 2021 20:54:40
DataPoint inactivated with code reason code Data not required.	Mariete Rendon (b) (4)	12 Nov 2020 19:28:13
User entered 'No (N)'	Mariete Rendon (b) (4)	21 Sep 2020 15:32:08

US3172250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:35:11
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4)	05 Apr 2021 20:55:34
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	05 Apr 2021 20:54:40
DataPoint inactivated with code reason code Data not required.	Mariete Rendon (b) (4)	12 Nov 2020 19:28:13
User entered '13 Sep 2020'	Mariete Rendon (b) (4)	21 Sep 2020 15:32:08

US3172250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:09

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:35:11
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	05 Apr 2021 20:54:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Mariete Rendon (b) (4)	12 Nov 2020 19:28:13
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	21 Sep 2020 15:32:08
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:09

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:54:40
DataPoint inactivated with code reason code Data not required.	Mariete Rendon (b) (4) (b) (4)	12 Nov 2020 19:28:13
User entered empty.	System	21 Sep 2020 15:32:08

US3172250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:09

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:35:11
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Jessie Downs (b) (4)	05 Apr 2021 20:55:34
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	05 Apr 2021 20:54:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Mariete Rendon (b) (4)	12 Nov 2020 19:28:13
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4)	
	Mariete Rendon (b) (4)	21 Sep 2020 15:32:08
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:35:11
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:54:40
DataPoint inactivated with code reason code Data not required.	Mariete Rendon (b) (4) (b) (4)	12 Nov 2020 19:28:13
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 15:32:08

US3172250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:09

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:35:11
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:54:40
DataPoint inactivated with code reason code Data not required.	Mariete Rendon (b) (4) (b) (4)	12 Nov 2020 19:28:13
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 15:32:08

US3172250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:09

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:35:11
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:54:40
DataPoint inactivated with code reason code Data not required.	Mariete Rendon (b) (4) (b) (4)	12 Nov 2020 19:28:13
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 15:32:08

US3172250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:35:11
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:54:40
DataPoint inactivated with code reason code Data not required.	Mariete Rendon (b) (4) (b) (4)	12 Nov 2020 19:28:13
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 15:32:08

US3172250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:35:11
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	05 Apr 2021 20:54:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Mariete Rendon (b) (4)	12 Nov 2020 19:28:13
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	21 Sep 2020 15:32:08
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:09

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:35:11
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	05 Apr 2021 20:54:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Mariete Rendon (b) (4)	12 Nov 2020 19:28:13
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	21 Sep 2020 15:32:08
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:09

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:35:11
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:54:40
DataPoint inactivated with code reason code Data not required.	Mariete Rendon (b) (4) (b) (4)	12 Nov 2020 19:28:13
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 15:32:08

US3172250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:09

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:35:11
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	05 Apr 2021 20:54:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Mariete Rendon (b) (4)	12 Nov 2020 19:28:13
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	21 Sep 2020 15:32:08
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:35:11
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	05 Apr 2021 20:54:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Mariete Rendon (b) (4)	12 Nov 2020 19:28:13
User entered '0'	(b) (4)	
	Mariete Rendon (b) (4)	21 Sep 2020 15:32:08
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:35:11
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	05 Apr 2021 20:54:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	12 Nov 2020 19:28:13
	(b) (4)	
	Mariete Rendon (b) (4)	21 Sep 2020 15:32:08
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:09

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:35:11
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:54:40
DataPoint inactivated with code reason code Data not required.	Mariete Rendon (b) (4) (b) (4)	12 Nov 2020 19:28:13
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 15:32:08

US3172250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:09

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:35:11
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	05 Apr 2021 20:54:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Mariete Rendon (b) (4)	12 Nov 2020 19:28:13
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Mariete Rendon (b) (4)	21 Sep 2020 15:32:08
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:09

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:35:11
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:54:40
DataPoint inactivated with code reason code Data not required.	Mariete Rendon (b) (4) (b) (4)	12 Nov 2020 19:28:13
User entered 'Not Related (NOT RELATED)'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 15:32:08

US3172250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:09

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:35:11
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Apr 2021 20:45:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Apr 2021 20:45:41
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Jessie Downs (b) (4)	06 Apr 2021 20:45:41
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 20:55:34
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4)	05 Apr 2021 20:55:34
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	05 Apr 2021 20:54:40
DataPoint inactivated with code reason code Data not required.	Mariete Rendon (b) (4)	12 Nov 2020 19:28:13
User entered 'None (NONE)'	Mariete Rendon (b) (4)	21 Sep 2020 15:32:08

US3172250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:09

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:35:11
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	05 Apr 2021 20:54:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Mariete Rendon (b) (4)	12 Nov 2020 19:28:13
User entered '0'	(b) (4)	
	Mariete Rendon (b) (4)	21 Sep 2020 15:32:08
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:35:11
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	05 Apr 2021 20:54:40
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Mariete Rendon (b) (4)	12 Nov 2020 19:28:13
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.	(b) (4)	
' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 02:50:07
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.	Mariete Rendon (b) (4)	13 Oct 2020 13:38:08
' answered with 'Conmed unknown at this time. Multiple attempts made to get records.' (Site from DM).	(b) (4)	
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.	(b) (4), (b) (6)	13 Oct 2020 03:51:53
' (Site from DM).		
User entered 'I'	Mariete Rendon (b) (4)	21 Sep 2020 15:32:08
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:09

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:35:11
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:54:40
DataPoint inactivated with code reason code Data not required.	Mariete Rendon (b) (4) (b) (4)	12 Nov 2020 19:28:13
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 15:32:08

US3172250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:09

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:35:11
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Jessie Downs (b) (4)	05 Apr 2021 20:55:34
DataPoint activated with code reason code Data required.	(b) (4)	05 Apr 2021 20:54:40
DataPoint inactivated with code reason code Data not required.	Mariete Rendon (b) (4)	12 Nov 2020 19:28:13
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4)	21 Sep 2020 15:32:08

US3172250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:09

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:35:11
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:54:40
DataPoint inactivated with code reason code Data not required.	Mariete Rendon (b) (4) (b) (4)	12 Nov 2020 19:28:13
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 15:32:08

US3172250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:09

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:35:11
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:54:40
DataPoint inactivated with code reason code Data not required.	Mariete Rendon (b) (4) (b) (4)	12 Nov 2020 19:28:13
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 15:32:08

US3172250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:09

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:54:40
DataPoint inactivated with code reason code Data not required.	Mariete Rendon (b) (4) (b) (4)	12 Nov 2020 19:28:13
User entered '0'	System	21 Sep 2020 15:32:08

US3172250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:09

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	05 Apr 2021 20:55:34
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:54:40
DataPoint inactivated with code reason code Data not required.	Mariete Rendon (b) (4) (b) (4)	12 Nov 2020 19:28:13
User entered '1'	System	21 Sep 2020 15:32:08

US3172250

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:34:09

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:54:40
DataPoint inactivated with code reason code Data not required.	Mariete Rendon (b) (4) (b) (4)	12 Nov 2020 19:28:13

US3172250

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:09

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:32:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:37:26
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:54:11
User entered 'USA-US118-2020-mRNA-1273-P301000010'	System	13 Nov 2020 17:52:56
User entered 'New'	(b) (4), (b) (6)	13 Nov 2020 17:52:56

US3172250

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:09

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:32:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:37:26
User closed query 'Per DM CLR - RQ: Site's response noted. However, there is no MH of CONGESTION HEART FAILURE. Clarify if this condition is an exacerbation of a baseline condition. If so, please add the corresponding condition to the Med History eCRF. Otherwise, consider deleting the term "exacerbation" from this event. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 20:21:20
Query 'Per DM CLR - RQ: Site's response noted. However, there is no MH of CONGESTION HEART FAILURE. Clarify if this condition is an exacerbation of a baseline condition. If so, please add the corresponding condition to the Med History eCRF. Otherwise, consider deleting the term "exacerbation" from this event. ' answered with 'See medical history #11' (Site from DM).	Mariete Rendon (b) (4) (b) (4)	22 Jan 2021 22:24:59
User opened query 'Per DM CLR - RQ: Site's response noted. However, there is no MH of CONGESTION HEART FAILURE. Clarify if this condition is an exacerbation of a baseline condition. If so, please add the corresponding condition to the Med History eCRF. Otherwise, consider deleting the term "exacerbation" from this event. ' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 05:59:23
User closed query 'Per DM CLR: EXACERBATION AE is noted, but no baseline medical history or adverse event condition is found. Please confirm if this is a worsening; if yes, please add baseline Medical history or prior AE to the appropriate page as applicable. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 12:36:39

US3172250

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:09

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: EXACERBATION AE is noted, but no baseline medical history or adverse event condition is found. Please confirm if this is a worsening; if yes, please add baseline Medical history or prior AE to the appropriate page as applicable. ' answered with 'Medical history was updated. ' (Site from DM).	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:15:24
User opened query 'Per DM CLR: EXACERBATION AE is noted, but no baseline medical history or adverse event condition is found. Please confirm if this is a worsening; if yes, please add baseline Medical history or prior AE to the appropriate page as applicable. ' (Site from DM).	(b) (4), (b) (6) (b) (4)	21 Nov 2020 15:05:23
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure congestive, LLT: Congestive cardiac failure aggravated - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 23:25:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 23:25:36
Data point term sent to Coder	System	12 Nov 2020 19:28:02
User entered 'acute exacerbation of congestion heart failure'	Mariete Rendon (b) (4) (b) (4)	12 Nov 2020 19:27:36

US3172250

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:09

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:37:26
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:18:17
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	12 Nov 2020 19:27:36

US3172250

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:09

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:37:26
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:18:22
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	12 Nov 2020 19:27:36

US3172250

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:37:26
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 17:18:24
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	12 Nov 2020 19:27:36

US3172250

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:32:29
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
User entered '12 Sep 2020'	Mariete Rendon (b) (4)	12 Nov 2020 19:27:36
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:09

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:32:29
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	12 Nov 2020 19:27:36
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:09

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 19:27:36

US3172250

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:32:29
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	12 Nov 2020 19:27:36
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:32:29
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
User entered '16 Sep 2020'	Mariete Rendon (b) (4)	12 Nov 2020 19:27:36
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:09

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:32:29
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	12 Nov 2020 19:27:36
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:09

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 19:27:36

US3172250

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:09

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 20:15:42
Query 'per source, grade 4.' canceled (Site from CRA).	(b) (4), (b) (6)	30 Apr 2021 20:15:41
User opened query 'per source, grade 4.' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 16:32:57
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 16:32:46
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:32:29
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Mariete Rendon (b) (4)	12 Nov 2020 19:27:36
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:32:29
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	12 Nov 2020 19:27:36
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:09

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:32:29
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	12 Nov 2020 19:27:36
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:09

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:32:29
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	12 Nov 2020 19:27:36
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:32:29
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
User entered 'I'	Mariete Rendon (b) (4)	12 Nov 2020 19:27:36
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:32:29
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
User entered '12 Sep 2020'	Mariete Rendon (b) (4)	12 Nov 2020 19:27:36
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:09

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:32:29
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
User entered '16 Sep 2020'	Mariete Rendon (b) (4)	12 Nov 2020 19:27:36
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:09

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:32:29
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	12 Nov 2020 19:27:36
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:09

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:32:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:37:26
User entered empty.	Mariete Rendon (b) (4) (b) (4)	12 Nov 2020 19:27:36

US3172250

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:32:29
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	12 Nov 2020 19:27:36
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:32:29
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	12 Nov 2020 19:27:36
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:09

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:32:29
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	12 Nov 2020 19:27:36
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:09

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:32:29
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Mariete Rendon (b) (4)	12 Nov 2020 19:27:36
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:09

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:32:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:37:26
User entered 'Not Related (NOT RELATED)'	Mariete Rendon (b) (4) (b) (4)	12 Nov 2020 19:27:36

US3172250

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:09

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:32:29
User closed query 'PV Query: As the subject received second dose of study drug after event. Please consider updating action taken to No change.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 18:28:55
Query 'PV Query: As the subject received second dose of study drug after event. Please consider updating action taken to No change.' answered with 'Data confirmed as entered. ' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 21:53:50
User opened query 'PV Query: As the subject received second dose of study drug after event. Please consider updating action taken to No change.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 17:35:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:37:26
User closed query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 13:25:28
Query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' answered with 'Data updated. Subject received both doses.' (Site from Safety).	Mariete Rendon (b) (4) (b) (4)	01 Dec 2020 20:11:42
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	01 Dec 2020 20:10:34
User opened query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 15:28:56
User entered 'None (NONE)'	Mariete Rendon (b) (4) (b) (4)	12 Nov 2020 19:27:36

US3172250

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:09

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:32:29
Signature has been broken.	Jessie Downs (b) (4)	05 Apr 2021 20:43:38
User signature succeeded.	(b) (4) Mark Kutner (b) (4)	23 Feb 2021 14:37:26
User entered '0'	(b) (4) Mariete Rendon (b) (4)	12 Nov 2020 19:27:36

US3172250

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:32:29
Signature has been broken.	Jessie Downs (b) (4)	16 Apr 2021 19:53:47
User signature succeeded.	(b) (4) Mark Kutner (b) (4)	23 Feb 2021 14:37:26
User entered 'l'	(b) (4) Mariete Rendon (b) (4)	12 Nov 2020 19:27:36

US3172250

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:09

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 20:15:53
DataPoint Un-verified.	Jessie Downs (b) (4)	23 Apr 2021 17:16:15
Signature has been broken.	(b) (4)	
	Jessie Downs (b) (4)	23 Apr 2021 17:16:15
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Jessie Downs (b) (4)	23 Apr 2021 17:16:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 16:32:29
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
User entered '0'	(b) (4)	
	Mariete Rendon (b) (4)	12 Nov 2020 19:27:36
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:09

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:32:29
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Mariete Rendon (b) (4)	12 Nov 2020 19:27:36
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:09

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:32:29
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:37:26
User entered empty.	Mariete Rendon (b) (4) (b) (4)	12 Nov 2020 19:27:36

US3172250

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:09

[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. Please leave query open until information is obtained.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 15:52:19
	(b) (4), (b) (6)	30 Apr 2021 20:16:05
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until information is obtained.' answered with 'Narrative was updated with relevant laboratory test results performed on subject 12Sep2020.' (Site from Safety). Signature has been broken.	Jessie Downs (b) (4) (b) (4)	30 Apr 2021 18:58:46
	Jessie Downs (b) (4) (b) (4)	30 Apr 2021 18:57:52
User entered 'ON DAY 27TH VISIT SUBJECT REPORTED AN A/E: ON 12SEP2020 BILATERAL LOWER EXTRMITY EDEMA REASON WHY HE WENT TO BROWARD HOSPITAL, DENIED ADMISSION. TODAY SITE RECEIVED MEDICAL RECORDS THAT REVEALED SUBJECT ADMISSION FOR 4 DAYS DUE TO ACUTE EXACERBATION OF CONGESTION HEART FAILURE. A/E WAS UPDATED TO SAE. RELEVANT LABORATORY AND DIAGNOSTIC TEST RESULTS THAT WERE PERFORMED ON SUBJECT WAS TROPONIN I ON 12SEP2020 AT 18:38 WITH RESULTS OF 0.03. AT 10:38 SUBJECTS TROPONIN I RESULTS WAS 0.04. LASTLY SUBJECTS TROPONIN RESULTS AT 1:19 REMAINED AT 0.04. ALL THREE LABS WERE PERFORMED ON 12SEP2020.' reason for change: Data Entry Error DataPoint Un-verified.	Jessie Downs (b) (4) (b) (4)	30 Apr 2021 18:57:52
	(b) (4), (b) (6)	19 Apr 2021 16:33:18
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:32:29

US3172250

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:09

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until information is obtained.' (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 17:44:29
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 15:30:27
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'pending medical records' (Site from Safety).	Jessie Downs (b) (4)	11 Mar 2021 19:52:26
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	05 Mar 2021 15:20:21
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 18:28:58
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'pending' (Site from Safety).	Jessie Downs (b) (4)	26 Feb 2021 21:54:05
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 17:34:42
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
User closed query 'PV Query: Thanks you for updating action taken. Please update dosage information including date for 2nd dose of SD.' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 15:38:21
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	19 Feb 2021 15:38:16

US3172250

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:09

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Thanks you for updating action taken. Please update dosage information including date for 2nd dose of SD. ' answered with 'pending medical records' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	18 Feb 2021 20:45:57
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' answered with 'pending medical records' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	18 Feb 2021 20:45:54
User opened query 'PV Query: Thanks you for updating action taken. Please update dosage information including date for 2nd dose of SD. ' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 17:36:59
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 17:35:27
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 13:25:35
User closed query 'PV Query: Please clarify when the subject experienced bilateral lower extremity edema.' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 13:25:31
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'See medical history.' (Site from Safety).	Mariete Rendon (b) (4) (b) (4)	01 Dec 2020 20:12:02
Query 'PV Query: Please clarify when the subject experienced bilateral lower extremity edema.' answered with 'Data updated' (Site from Safety).	Mariete Rendon (b) (4) (b) (4)	01 Dec 2020 20:11:49
User entered 'ON DAY 27TH VISIT SUBJECT REPORTED AN A/E: On 12SEP2020 BILATERAL LOWER EXTRMITY EDEMA REASON WHY HE WENT TO BROWARD HOSPITAL, DENIED ADMISSION. TODAY SITE RECEIVED MEDICAL RECORDS THAT REVEALED SUBJECT ADMISSION FOR 4 DAYS DUE TO ACUTE EXACERBATION OF CONGESTION HEART FAILURE. A/E WAS UPDATED TO SAE.' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	01 Dec 2020 20:11:14
User closed query 'PV Query: Was the subject tested for COVID-19 during hospitalization? If yes, please provide results.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 12:40:21

PRODUCTION RELEASE (v12.003
EAB) (1725)

2252 of 4086

US3172250

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:09

[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.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 12:40:20
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 12:40:18
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Lab procedures added.' (Site from Safety).	Jessie Downs (b) (4)	24 Nov 2020 21:34:49
Query 'PV Query: Was the subject tested for COVID-19 during hospitalization? If yes, please provide results.' answered with 'No' (Site from Safety).	Jessie Downs (b) (4)	24 Nov 2020 21:33:55
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Concomitant Medication updated.' (Site from Safety).	Jessie Downs (b) (4)	24 Nov 2020 21:33:37
User opened query 'PV Query: Was the subject tested for COVID-19 during hospitalization? If yes, please provide results.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 15:35:29
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 15:35:12
User opened query 'PV Query: Please clarify when the subject experienced bilateral lower extremity edema.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 15:35:03
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 15:29:13

PRODUCTION RELEASE (v12.003
EAB) (1725)

2253 of 4086

US3172250

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:09

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 15:29:07
User entered 'On Day 27th visit subject reported an A/E: bilateral lower extremity edema reason why he went to broward hospital, denied admission. Today site received medical records that revealed subject admission for 4 days due to acute exacerbation of congestion heart failure. A/E was updated to SAE.'	Mariete Rendon (b) (4)	12 Nov 2020 19:27:36

US3172250

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:09

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Nov 2020 19:27:36

US3172250

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:09

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Nov 2020 19:27:36

US3172250

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:34:09

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Nov 2020 19:27:36

US3172250

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:09

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:31:20
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:19
User entered 'USA-US118-2021-mRNA-1273-P301000013'	System	25 Mar 2021 13:14:16
User entered 'New'	(b) (4), (b) (6)	25 Mar 2021 13:14:16

US3172250

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:09

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:31:20
User closed query 'Per DM CLR: Please confirm the AE term "LEFT SCIATIC EXACERBATION". as the associated baseline Med History condition is recorded as "RESOLVED". Clarify if this condition is an exacerbation of a baseline condition. If so, please add the corresponding condition to the Med History eCRF. Otherwise, consider deleting the term "exacerbation" from this event. ' (Site from DM). Query 'Per DM CLR: Please confirm the AE term "LEFT SCIATIC EXACERBATION". as the associated baseline Med History condition is recorded as "RESOLVED". Clarify if this condition is an exacerbation of a baseline condition. If so, please add the corresponding condition to the Med History eCRF. Otherwise, consider deleting the term "exacerbation" from this event. ' answered with 'unresolved' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 05:29:07
User opened query 'Per DM CLR: Please confirm the AE term "LEFT SCIATIC EXACERBATION". as the associated baseline Med History condition is recorded as "RESOLVED". Clarify if this condition is an exacerbation of a baseline condition. If so, please add the corresponding condition to the Med History eCRF. Otherwise, consider deleting the term "exacerbation" from this event. ' (Site from DM).	Mariete Rendon (b) (4)	14 Apr 2021 14:04:20
User opened query 'Per DM CLR: Please confirm the AE term "LEFT SCIATIC EXACERBATION". as the associated baseline Med History condition is recorded as "RESOLVED". Clarify if this condition is an exacerbation of a baseline condition. If so, please add the corresponding condition to the Med History eCRF. Otherwise, consider deleting the term "exacerbation" from this event. ' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 05:03:08
User coded data point as SOC: Nervous system disorders, HLG: Spinal cord and nerve root disorders, HLT: Lumbar spinal cord and nerve root disorders, PT: Sciatica, LLT: Sciatica aggravated - version MedDRA\23.0.	Coder Import (b) (4)	29 Mar 2021 13:57:06
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	29 Mar 2021 13:57:06
Data point term sent to Coder	System	24 Mar 2021 19:29:58
User entered 'left sciatic exacerbation'	Jessie Downs (b) (4)	24 Mar 2021 19:29:08

US3172250

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:09

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:31:20
User entered 'Yes (Y)'	Jessie Downs (b) (4)	24 Mar 2021 19:29:08
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:09

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:31:20
User entered 'No (N)'	Jessie Downs (b) (4)	24 Mar 2021 19:29:08
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:31:20
User entered 'No (N)'	Jessie Downs (b) (4)	24 Mar 2021 19:29:08
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:31:20
User entered '26 Feb 2021' reason for change: Data Entry Error	Jessie Downs (b) (4)	05 Apr 2021 21:04:04
User entered '27 Feb 2021'	Jessie Downs (b) (4)	24 Mar 2021 19:29:08

US3172250

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:09

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:31:20
User entered empty.	Jessie Downs (b) (4)	24 Mar 2021 19:29:08
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:09

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 19:29:08

US3172250

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
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). DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 21:31:11
	(b) (4), (b) (6)	19 Apr 2021 16:31:20
User entered 'Yes (Y)'	Jessie Downs (b) (4)	24 Mar 2021 19:29:08
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:31:20
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 10:24:28
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 'ongoing' (Site from Safety).	Mariete Rendon (b) (4)	14 Apr 2021 14:04:37
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)	02 Apr 2021 17:48:39
User entered empty.	Jessie Downs (b) (4)	24 Mar 2021 19:29:08

US3172250

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:09

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:31:20
User entered empty.	Jessie Downs (b) (4)	24 Mar 2021 19:29:08
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:09

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 19:29:08

US3172250

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:09

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:31:20
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jessie Downs (b) (4) (b) (4)	24 Mar 2021 19:29:08

US3172250

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:31:20
User entered 'Yes (Y)'	Jessie Downs (b) (4)	24 Mar 2021 19:29:08
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:09

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:31:20
User entered '0'	Jessie Downs (b) (4)	24 Mar 2021 19:29:08
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:09

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:31:20
User entered '0'	Jessie Downs (b) (4)	24 Mar 2021 19:29:08
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:31:20
User entered '1'	Jessie Downs (b) (4)	24 Mar 2021 19:29:08
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:31:20
User entered '26 Feb 2021' reason for change: Data Entry Error	Jessie Downs (b) (4)	05 Apr 2021 21:04:04
User entered '27 Feb 2021'	Jessie Downs (b) (4)	24 Mar 2021 19:29:08

US3172250

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:09

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User opened query 'PV Query: Discharge summary indicates that subject was discharged on 04 Mar 2021. Please confirm subject discharge date.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 16:00:28
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:31:20
User entered '03 Mar 2021' reason for change: Data Entry Error	Jessie Downs (b) (4)	05 Apr 2021 21:04:04
User entered '02 Mar 2021'	Jessie Downs (b) (4)	24 Mar 2021 19:29:08

US3172250

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:09

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:31:20
User entered 'No (N)'	Jessie Downs (b) (4)	24 Mar 2021 19:29:08
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:09

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:31:20
User entered empty.	Jessie Downs (b) (4)	24 Mar 2021 19:29:08
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:31:20
User entered '0'	Jessie Downs (b) (4)	24 Mar 2021 19:29:08
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:31:20
User entered '0'	Jessie Downs (b) (4)	24 Mar 2021 19:29:08
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:09

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:31:20
User entered '0'	Jessie Downs (b) (4)	24 Mar 2021 19:29:08
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:09

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:31:20
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	24 Mar 2021 19:29:08

US3172250

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:09

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:31:20
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	24 Mar 2021 19:29:08

US3172250

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:09

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:31:20
User entered 'None (NONE)'	Jessie Downs (b) (4)	24 Mar 2021 19:29:08
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:09

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:31:20
User entered '0'	Jessie Downs (b) (4)	24 Mar 2021 19:29:08
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:31:20
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, the ConMed #17 recorded was given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 05:29:13
User closed query 'PV Query: Oxycodone was listed as a concomitant medication and was used to treat the event left sciatic exacerbation. Please confirm if oxycodone should be considered just as a treatment medication since it was used for the treatment of the event.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 10:24:45
Query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, the ConMed #17 recorded was given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify.' answered with 'in use as PRN in previous exacerbation episodes' (Site from DM).	Mariete Rendon (b) (4)	14 Apr 2021 14:05:44
Query 'PV Query: Oxycodone was listed as a concomitant medication and was used to treat the event left sciatic exacerbation. Please confirm if oxycodone should be considered just as a treatment medication since it was used for the treatment of the event.' answered with 'as per investigator yes' (Site from Safety).	Mariete Rendon (b) (4)	14 Apr 2021 14:05:14
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, the ConMed #17 recorded was given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 05:03:25
User opened query 'PV Query: Oxycodone was listed as a concomitant medication and was used to treat the event left sciatic exacerbation. Please confirm if oxycodone should be considered just as a treatment medication since it was used for the treatment of the event.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 17:49:22
User entered 'I'	Jessie Downs (b) (4)	24 Mar 2021 19:29:08

PRODUCTION RELEASE (v12.003
EAB) (1725)

2286 of 4086

US3172250

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:09

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:31:20
User entered '0'	Jessie Downs (b) (4)	24 Mar 2021 19:29:08
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:09

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:31:20
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)	02 Apr 2021 17:48:50
Query '. PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' canceled (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 17:48:47
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)	02 Apr 2021 17:48:17
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jessie Downs (b) (4) (b) (4)	24 Mar 2021 19:29:08

US3172250

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:09

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:31:20
User entered empty.	Jessie Downs (b) (4)	24 Mar 2021 19:29:08
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:09

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 16:31:29
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:31:20
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 10:24:55
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. ' answered with 'Data updated' (Site from Safety).	Mariete Rendon (b) (4) (b) (4)	14 Apr 2021 14:08:42
User entered 'SUBJECT WITH PREVIOUSLY UNDISCLOSED LEFT SCIATICA ONGOING SINCE 2018 AS HISTORICAL CHRONIC LOWER BACK PAIN BOTH SECONDARY TO 3 HERNIATED LUMBAR DISCS. TAKING PRN OXYCODONE WHEN EXACERBATION AT THIS TIME WHEN HE REMAINED ADMITTED AT HIALEAH HOSPITAL FOR 4 DAYS BEING TRANSFERRED TO SAINT CATHERINE REHABILITATION CENTER WHERE HE STAYED FOR 1 WEEK BEING DISCHARGED WITH A STILL ONGOING SCIATIC LEFT LEG PAIN WITH INTENSITY FROM 6 TO 10 WHEN HE WAS ADMITTED. MEDICAL RECORDS HAVE BEEN REQUESTED AND ARE PENDING TO BE RECEIVED.Nasopharyngeal swab COVID-19 PCR test: 28FEB2021 @18:00 Results: Detected.' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	14 Apr 2021 14:08:14
Query 'PV Query: Oxycodone was listed as a concomitant medication and was used to treat the event left sciatic exacerbation. Please confirm if oxycodone should be considered just as a treatment medication since it was used for the treatment of the event. ' canceled (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 17:49:15

US3172250

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:09

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 17:49:04
Query '. PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so' canceled (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 17:48:57
User opened query '. PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 17:47:48
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 17:47:08
User opened query 'PV Query: Oxycodone was listed as a concomitant medication and was used to treat the event left sciatic exacerbation. Please confirm if oxycodone should be considered just as a treatment medication since it was used for the treatment of the event. ' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 17:46:57

US3172250

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:09

[Narrative](#)

Audit	User	Time (GMT)
User entered 'subject with previously undisclosed left sciatica ongoing since 2018 as historical chronic lower back pain both secondary to 3 herniated lumbar discs. taking prn oxycodone when exacerbation at this time when he remained admitted at Hialeah hospital for 4 days being transferred to saint Catherine rehabilitation center where he stayed for 1 week being discharged with a still ongoing sciatic left leg pain with intensity from 6 to 10 when he was admitted. Medical records have been requested and are pending to be received.'	Jessie Downs (b) (4)	24 Mar 2021 19:29:08

US3172250

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:09

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Mar 2021 19:29:08

US3172250

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:09

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Mar 2021 19:29:08

US3172250

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:34:09

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Mar 2021 19:29:08

US3172250

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:09

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:07:08
User entered 'USA-US118-2021-mRNA-1273-P301000013'	(b) (4), (b) (6)	06 Apr 2021 18:07:03

US3172250

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:09

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Chest pain - version MedDRA\\23.0.	Coder Import (b) (4)	05 Apr 2021 17:49:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Apr 2021 17:49:26
Data point term sent to Coder	System	05 Apr 2021 17:48:18
User entered 'Chest Pain'	Mariete Rendon (b) (4)	05 Apr 2021 17:47:35
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:09

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	05 Apr 2021 17:47:35

US3172250

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:09

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	05 Apr 2021 17:47:35

US3172250

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	05 Apr 2021 17:47:35

US3172250

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:09

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '26 Feb 2021'	Mariete Rendon (b) (4) (b) (4)	05 Apr 2021 17:47:35

US3172250

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:09

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Mariete Rendon (b) (4) (b) (4)	05 Apr 2021 17:47:35

US3172250

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:09

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 17:47:35

US3172250

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	05 Apr 2021 17:47:35

US3172250

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '27 Feb 2021'	Mariete Rendon (b) (4) (b) (4)	05 Apr 2021 17:47:35

US3172250

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:09

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Mariete Rendon (b) (4) (b) (4)	05 Apr 2021 17:47:35

US3172250

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:09

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 17:47:35

US3172250

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:09

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 3/Severe (Grade 3/Severe)'	Mariete Rendon (b) (4) (b) (4)	05 Apr 2021 17:47:35

US3172250

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	05 Apr 2021 17:47:35

US3172250

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:09

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Mariete Rendon (b) (4) (b) (4)	05 Apr 2021 17:47:35

US3172250

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:09

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Mariete Rendon (b) (4) (b) (4)	05 Apr 2021 17:47:35

US3172250

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered 'I'	Mariete Rendon (b) (4) (b) (4)	05 Apr 2021 17:47:35

US3172250

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '26 Feb 2021'	Mariete Rendon (b) (4) (b) (4)	05 Apr 2021 17:47:35

US3172250

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:09

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '03 Mar 2021'	Mariete Rendon (b) (4) (b) (4)	05 Apr 2021 17:47:35

US3172250

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:09

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	05 Apr 2021 17:47:35

US3172250

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:09

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Mariete Rendon (b) (4) (b) (4)	05 Apr 2021 17:47:35

US3172250

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Mariete Rendon (b) (4) (b) (4)	05 Apr 2021 17:47:35

US3172250

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Mariete Rendon (b) (4) (b) (4)	05 Apr 2021 17:47:35

US3172250

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:09

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Mariete Rendon (b) (4) (b) (4)	05 Apr 2021 17:47:35

US3172250

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:09

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Mariete Rendon (b) (4) (b) (4)	05 Apr 2021 17:47:35

US3172250

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:09

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Mariete Rendon (b) (4) (b) (4)	05 Apr 2021 17:47:35

US3172250

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:09

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please update action taken with study drug for events chest pain and NSTMI from not applicable to none/no change as events started after receiving mRNA-1273 and subject received final dose on schedule.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 16:04:03
User entered 'Not Applicable (NOT APPLICABLE)'	Mariete Rendon (b) (4)	05 Apr 2021 17:47:35

US3172250

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:09

[None](#)

Audit	User	Time (GMT)
User entered '0'	Mariete Rendon (b) (4) (b) (4)	05 Apr 2021 17:47:35

US3172250

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered 'I'	Mariete Rendon (b) (4) (b) (4)	05 Apr 2021 17:47:35

US3172250

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:09

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Mariete Rendon (b) (4) (b) (4)	05 Apr 2021 17:47:35

US3172250

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:09

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Mariete Rendon (b) (4) (b) (4)	05 Apr 2021 17:47:35

US3172250

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:09

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Mariete Rendon (b) (4) (b) (4)	05 Apr 2021 17:47:35

US3172250

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:09

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject that was admitted on that day complaint of chest pain with associated effort dyspnea and consistent with non st myocardial infection as described in respective AE.' reason for change: Data Entry Error	Jessie Downs (b) (4)	05 Apr 2021 20:43:24
User entered empty.	Mariete Rendon (b) (4)	05 Apr 2021 17:47:35

US3172250

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:09

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Apr 2021 17:47:35

US3172250

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:09

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Apr 2021 17:47:35

US3172250

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:34:09

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Apr 2021 17:47:35

US3172250

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:09

[AEID](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	05 Apr 2021 20:50:55
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	05 Apr 2021 20:43:38

US3172250

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:09

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Investigations, HLGT: Hepatobiliary investigations, HLT: Liver function analyses, PT: Liver function test increased, LLT: Liver function test increased - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Apr 2021 16:46:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Apr 2021 16:46:50
Data point term sent to Coder	System	23 Apr 2021 16:45:27
Coding entries removed.	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:45:25
User entered 'ELEVATED LIVER FUNCTION test' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:45:25
User coded data point as SOC: Investigations, HLGT: Hepatobiliary investigations, HLT: Liver function analyses, PT: Liver function test increased, LLT: Liver function test increased - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Apr 2021 20:55:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Apr 2021 20:55:34
Data point term sent to Coder	System	05 Apr 2021 20:54:15
User entered 'elevated liver function'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:54:04
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:50:55
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:43:38

US3172250

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:09

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessie Downs (b) (4)	05 Apr 2021 20:54:04
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	05 Apr 2021 20:50:55
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	05 Apr 2021 20:43:38

US3172250

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:09

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4)	05 Apr 2021 20:54:04
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	05 Apr 2021 20:50:55
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	05 Apr 2021 20:43:38

US3172250

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4)	05 Apr 2021 20:54:04
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	05 Apr 2021 20:50:55
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	05 Apr 2021 20:43:38

US3172250

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '01 Mar 2021'	Jessie Downs (b) (4)	05 Apr 2021 20:54:04
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	05 Apr 2021 20:50:55
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	05 Apr 2021 20:43:38

US3172250

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:09

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 20:54:04
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	05 Apr 2021 20:50:55
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	05 Apr 2021 20:43:38

US3172250

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:09

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 20:54:04
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	05 Apr 2021 20:50:55
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	05 Apr 2021 20:43:38

US3172250

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessie Downs (b) (4)	05 Apr 2021 20:54:04
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	05 Apr 2021 20:50:55
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	05 Apr 2021 20:43:38

US3172250

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 20:54:04
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	05 Apr 2021 20:50:55
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	05 Apr 2021 20:43:38

US3172250

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:09

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 20:54:04
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	05 Apr 2021 20:50:55
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	05 Apr 2021 20:43:38

US3172250

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:09

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 20:54:04
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	05 Apr 2021 20:50:55
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	05 Apr 2021 20:43:38

US3172250

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:09

[Severity](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Apr 2021 20:45:22
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Apr 2021 20:45:22
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Jessie Downs (b) (4)	06 Apr 2021 20:45:22
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 20:54:04
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 20:54:04
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	05 Apr 2021 20:50:55
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	05 Apr 2021 20:43:38

US3172250

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4)	05 Apr 2021 20:54:04
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	05 Apr 2021 20:50:55
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	05 Apr 2021 20:43:38

US3172250

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:09

Death

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4)	05 Apr 2021 20:54:04
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	05 Apr 2021 20:50:55
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	05 Apr 2021 20:43:38

US3172250

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:09

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4)	05 Apr 2021 20:54:04
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	05 Apr 2021 20:50:55
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	05 Apr 2021 20:43:38

US3172250

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4)	05 Apr 2021 20:54:04
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	05 Apr 2021 20:50:55
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	05 Apr 2021 20:43:38

US3172250

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 20:54:04
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	05 Apr 2021 20:50:55
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	05 Apr 2021 20:43:38

US3172250

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:09

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 20:54:04
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	05 Apr 2021 20:50:55
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	05 Apr 2021 20:43:38

US3172250

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:09

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 20:54:04
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	05 Apr 2021 20:50:55
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	05 Apr 2021 20:43:38

US3172250

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:09

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 20:54:04
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	05 Apr 2021 20:50:55
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	05 Apr 2021 20:43:38

US3172250

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4)	05 Apr 2021 20:54:04
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	05 Apr 2021 20:50:55
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	05 Apr 2021 20:43:38

US3172250

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4)	05 Apr 2021 20:54:04
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	05 Apr 2021 20:50:55
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	05 Apr 2021 20:43:38

US3172250

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:09

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4)	05 Apr 2021 20:54:04
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	05 Apr 2021 20:50:55
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	05 Apr 2021 20:43:38

US3172250

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:09

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4)	05 Apr 2021 20:54:04
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	05 Apr 2021 20:50:55
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	05 Apr 2021 20:43:38

US3172250

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:09

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4)	05 Apr 2021 20:54:04
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	05 Apr 2021 20:50:55
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	05 Apr 2021 20:43:38

US3172250

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:09

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Jessie Downs (b) (4)	05 Apr 2021 20:54:04
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	05 Apr 2021 20:50:55
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	05 Apr 2021 20:43:38

US3172250

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:09

None

Audit	User	Time (GMT)
User entered '1'	Jessie Downs (b) (4)	05 Apr 2021 20:54:04
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	05 Apr 2021 20:50:55
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	05 Apr 2021 20:43:38

US3172250

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4)	05 Apr 2021 20:54:04
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	05 Apr 2021 20:50:55
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	05 Apr 2021 20:43:38

US3172250

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:09

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4)	05 Apr 2021 20:54:04
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	05 Apr 2021 20:50:55
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	05 Apr 2021 20:43:38

US3172250

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:09

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Jessie Downs (b) (4)	23 Apr 2021 16:49:14
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jessie Downs (b) (4)	05 Apr 2021 20:54:04
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	05 Apr 2021 20:50:55
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	05 Apr 2021 20:43:38

US3172250

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:09

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 20:54:04
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	05 Apr 2021 20:50:55
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	05 Apr 2021 20:43:38

US3172250

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:09

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 20:54:04
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	05 Apr 2021 20:50:55
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	05 Apr 2021 20:43:38

US3172250

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:09

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	05 Apr 2021 20:54:04
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	05 Apr 2021 20:50:55
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	05 Apr 2021 20:43:38

US3172250

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:09

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 20:54:04
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	05 Apr 2021 20:50:55
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	05 Apr 2021 20:43:38

US3172250

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:34:09

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Jessie Downs (b) (4)	05 Apr 2021 20:50:55
DataPoint inactivated with code reason code Data not required.	Jessie Downs (b) (4)	05 Apr 2021 20:43:38

US3172250

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:09

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:09:15
User entered 'USA-US118-2021-mRNA-1273-P301000013'	(b) (4), (b) (6)	06 Apr 2021 18:09:08

US3172250

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:09

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Acute myocardial infarction, LLT: Non STEMI - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Apr 2021 10:21:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Apr 2021 10:21:55
Data point term sent to Coder	System	05 Apr 2021 17:50:21
User entered 'Non ST Myocardial Infarction (NSTMI)'	Mariete Rendon (b) (4) (b) (4)	05 Apr 2021 17:49:31

US3172250

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:09

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	05 Apr 2021 17:49:31

US3172250

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:09

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	05 Apr 2021 17:49:31

US3172250

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	05 Apr 2021 17:49:31

US3172250

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:09

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '26 Feb 2021'	Mariete Rendon (b) (4) (b) (4)	05 Apr 2021 17:49:31

US3172250

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:09

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Mariete Rendon (b) (4) (b) (4)	05 Apr 2021 17:49:31

US3172250

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:09

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 17:49:31

US3172250

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	05 Apr 2021 17:49:31

US3172250

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '01 Mar 2021'	Mariete Rendon (b) (4) (b) (4)	05 Apr 2021 17:49:31

US3172250

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:09

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Mariete Rendon (b) (4) (b) (4)	05 Apr 2021 17:49:31

US3172250

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:09

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 17:49:31

US3172250

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:09

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 3/Severe (Grade 3/Severe)'	Mariete Rendon (b) (4) (b) (4)	05 Apr 2021 17:49:31

US3172250

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	23 Apr 2021 17:58:58
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	23 Apr 2021 17:09:01
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	05 Apr 2021 17:49:31

US3172250

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:09

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Mariete Rendon (b) (4) (b) (4)	05 Apr 2021 17:49:31

US3172250

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:09

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Mariete Rendon (b) (4) (b) (4)	05 Apr 2021 17:49:31

US3172250

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	23 Apr 2021 17:58:58
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		23 Apr 2021 17:58:58
User entered '1' reason for change: Data Entry Error	Jessie Downs (b) (4)	23 Apr 2021 17:58:58
	(b) (4)	
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	23 Apr 2021 17:09:01
User entered '0' reason for change: Data Entry Error	Jessie Downs (b) (4)	23 Apr 2021 17:09:01
	(b) (4)	
User entered '1'	Mariete Rendon (b) (4)	05 Apr 2021 17:49:31
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '26 Feb 2021'	Mariete Rendon (b) (4) (b) (4)	05 Apr 2021 17:49:31

US3172250

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:09

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Discharge summary indicates that subject was discharged on 04 Mar 2021. Please confirm subject discharge date.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 16:03:02
User entered '03 Mar 2021'	Mariete Rendon (b) (4)	05 Apr 2021 17:49:31

US3172250

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:09

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	05 Apr 2021 17:49:31

US3172250

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:09

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Mariete Rendon (b) (4) (b) (4)	05 Apr 2021 17:49:31

US3172250

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Mariete Rendon (b) (4) (b) (4)	05 Apr 2021 17:49:31

US3172250

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Mariete Rendon (b) (4) (b) (4)	05 Apr 2021 17:49:31

US3172250

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:09

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Mariete Rendon (b) (4) (b) (4)	05 Apr 2021 17:49:31

US3172250

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:09

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Mariete Rendon (b) (4) (b) (4)	05 Apr 2021 17:49:31

US3172250

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:09

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Mariete Rendon (b) (4) (b) (4)	05 Apr 2021 17:49:31

US3172250

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:09

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please update action taken with study drug for events chest pain and NSTMI from not applicable to none/no change as events started after receiving mRNA-1273 and subject received final dose on schedule.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 16:02:48
User entered 'Not Applicable (NOT APPLICABLE)'	Mariete Rendon (b) (4)	05 Apr 2021 17:49:31

US3172250

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:09

[None](#)

Audit	User	Time (GMT)
User entered '0'	Mariete Rendon (b) (4) (b) (4)	05 Apr 2021 17:49:31

US3172250

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered 'I'	Mariete Rendon (b) (4) (b) (4)	05 Apr 2021 17:49:31

US3172250

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:09

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Mariete Rendon (b) (4) (b) (4)	05 Apr 2021 17:49:31

US3172250

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:09

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Mariete Rendon (b) (4) (b) (4)	05 Apr 2021 17:49:31

US3172250

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:09

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Mariete Rendon (b) (4) (b) (4)	05 Apr 2021 17:49:31

US3172250

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:09

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Consultation report from 02 Mar 2021 states subject tested positive for COVID-19. Please confirm whether COVID-19 should be reported as a serious/non-serious event, as applicable.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 16:03:21
User entered 'SUBJECT THAT BEING ADMITTED WITH CHEST PAIN HAS TROPONIN I LEVELS OF 0.057 MG/ML on 26FEB2021 CONSISTENT WITH NSTMI THAT RESOLVED 3 DAYS WITH TROPONIN NORMAL LEVELS OF 0.031 on 01MAR2021.'	Mariete Rendon (b) (4)	13 Apr 2021 19:38:28
reason for change: Data Entry Error	(b) (4)	
User entered 'subject that being admitted with chest pain has troponin i levels of 0.057mg/ml consistent with nstmi that resolved 3 days. days with troponin normal levels of 0.031.' reason for change: Data Entry Error	Jessie Downs (b) (4)	05 Apr 2021 20:50:09
User entered empty.	(b) (4)	
	Mariete Rendon (b) (4)	05 Apr 2021 17:49:31
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:09

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Apr 2021 17:49:31

US3172250

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:09

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Apr 2021 17:49:31

US3172250

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:34:09

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Apr 2021 17:49:31

US3172250

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:34:09

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: Asymptomatic COVID-19, LLT: Asymptomatic COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Apr 2021 20:59:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Apr 2021 20:59:41
Data point term sent to Coder	System	05 Apr 2021 20:58:21
User entered 'asymptomatic covid 19 infection'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:57:20

US3172250

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:34:09

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:57:20

US3172250

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:34:09

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:57:20

US3172250

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:34:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Query 'Please review and correct as you have already noted that this was not a symptomatic case. This should only be yes if the subject was indeed symptomatic.' answered with 'Data was updated.' (Site from CRA).	Jessie Downs (b) (4)	30 Apr 2021 18:39:45
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	30 Apr 2021 18:39:21
User opened query 'Please review and correct as you have already noted that this was not a symptomatic case. This should only be yes if the subject was indeed symptomatic.' (Site from CRA).	(b) (4), (b) (6)	28 Apr 2021 19:16:15
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Apr 2021 20:46:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Apr 2021 20:46:09
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4)	06 Apr 2021 20:46:09
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 20:57:20
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 20:57:20

US3172250

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:34:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '28 Feb 2021'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:57:20

US3172250

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:34:09

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:57:20

US3172250

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:34:09

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 20:57:20

US3172250

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	23 Apr 2021 16:56:00
User entered 'Yes (Y)'	Jessie Downs (b) (4)	05 Apr 2021 20:57:20

US3172250

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	23 Apr 2021 16:56:27
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	23 Apr 2021 16:56:27
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	23 Apr 2021 16:56:00
User entered '11 Mar 2021' reason for change: Data Entry Error	Jessie Downs (b) (4)	23 Apr 2021 16:56:00
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 20:57:20

US3172250

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:34:09

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:57:20

US3172250

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:34:09

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 20:57:20

US3172250

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:34:09

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:57:20

US3172250

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:34:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:57:20

US3172250

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:34:09

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:57:20

US3172250

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:34:09

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:57:20

US3172250

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:34:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:57:20

US3172250

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:34:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:57:20

US3172250

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:34:09

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:57:20

US3172250

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:34:09

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:57:20

US3172250

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:34:09

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:57:20

US3172250

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:34:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:57:20

US3172250

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:34:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:57:20

US3172250

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:34:09

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:57:20

US3172250

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:34:09

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:57:20

US3172250

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:34:09

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:57:20

US3172250

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:34:09

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:57:20

US3172250

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:34:09

[None](#)

Audit	User	Time (GMT)
User entered 'I'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:57:20

US3172250

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:34:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:57:20

US3172250

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:34:09

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:57:20

US3172250

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:34:09

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Apr 2021 18:06:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Apr 2021 18:06:05
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 18:06:05
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Apr 2021 16:56:27
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:56:27
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:57:20

US3172250

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:34:09

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:57:20

US3172250

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:34:09

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:57:20

US3172250

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:34:09

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Apr 2021 20:57:20

US3172250

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:34:09

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Apr 2021 20:57:20

US3172250

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:34:09

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLGT: Myocardial disorders, HLT: Myocardial disorders NEC, PT: Cardiomegaly, LLT: Cardiomegaly - version MedDRA\\23.0.	Coder Import (b) (4)	05 Apr 2021 21:01:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Apr 2021 21:01:06
Data point term sent to Coder	System	05 Apr 2021 20:59:22
User entered 'cardiomegaly'	Jessie Downs (b) (4)	05 Apr 2021 20:59:21
	(b) (4)	

US3172250

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:34:09

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:59:21

US3172250

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:34:09

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:59:21

US3172250

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:34:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:59:21

US3172250

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:34:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:59:21

US3172250

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:34:09

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:59:21

US3172250

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:34:09

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 20:59:21

US3172250

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:59:21

US3172250

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:59:21

US3172250

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:34:09

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:59:21

US3172250

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:34:09

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 20:59:21

US3172250

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:34:09

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:59:21

US3172250

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:34:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:59:21

US3172250

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:34:09

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:59:21

US3172250

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:34:09

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:59:21

US3172250

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:34:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:59:21

US3172250

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:34:09

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:59:21

US3172250

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:34:09

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:59:21

US3172250

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:34:09

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:59:21

US3172250

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:34:09

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:59:21

US3172250

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:34:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:59:21

US3172250

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:34:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:59:21

US3172250

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:34:09

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:59:21

US3172250

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:34:09

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:59:21

US3172250

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:34:09

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:59:21

US3172250

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:34:09

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:59:21

US3172250

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:34:09

[None](#)

Audit	User	Time (GMT)
User entered 'I'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:59:21

US3172250

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:34:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:59:21

US3172250

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:34:09

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:59:21

US3172250

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:34:09

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:59:21

US3172250

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:34:09

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:59:21

US3172250

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:34:09

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 20:59:21

US3172250

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:34:09

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Apr 2021 20:59:21

US3172250

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:34:09

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Apr 2021 20:59:21

US3172250

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:34:09

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Peritoneal and retroperitoneal conditions, HLT: Peritoneal and retroperitoneal disorders, PT: Ascites, LLT: Ascites - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Apr 2021 10:04:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Apr 2021 10:04:55
Data point term sent to Coder	System	05 Apr 2021 21:01:35
User entered 'upper abdominal ascites'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:01:14

US3172250

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:34:09

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:01:14

US3172250

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:34:09

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:01:14

US3172250

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:34:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:01:14

US3172250

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:34:09

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Sep 2020'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:01:14

US3172250

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:34:09

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:01:14

US3172250

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:34:09

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 21:01:14

US3172250

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:01:14

US3172250

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '15 Sep 2020'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:01:14

US3172250

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:34:09

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:01:14

US3172250

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:34:09

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 21:01:14

US3172250

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:34:09

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:01:14

US3172250

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:34:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:01:14

US3172250

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:34:09

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:01:14

US3172250

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:34:09

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:01:14

US3172250

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:34:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:01:14

US3172250

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:34:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:01:14

US3172250

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:34:09

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:01:14

US3172250

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:34:09

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:01:14

US3172250

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:34:09

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:01:14

US3172250

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:34:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:01:14

US3172250

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:34:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:01:14

US3172250

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:34:09

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:01:14

US3172250

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:34:09

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:01:14

US3172250

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:34:09

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:01:14

US3172250

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:34:09

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:01:14

US3172250

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:34:09

[None](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:01:14

US3172250

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:34:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered 'I'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:01:14

US3172250

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:34:09

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:01:14

US3172250

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:34:09

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:01:14

US3172250

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:34:09

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:01:14

US3172250

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:34:09

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:01:14

US3172250

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:34:09

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Apr 2021 21:01:14

US3172250

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:34:09

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Apr 2021 21:01:14

US3172250

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:34:09

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc degeneration, LLT: Degenerative disc disease - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 12:26:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 12:26:55
Data point term sent to Coder	System	05 Apr 2021 21:02:46
User entered 'degenerative l4-5 posterior disc bulge'	Jessie Downs (b) (4)	05 Apr 2021 21:02:39

US3172250

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:34:09

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:02:39

US3172250

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:34:09

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:02:39

US3172250

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:34:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:02:39

US3172250

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:34:09

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Sep 2020'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:02:39

US3172250

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:34:09

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:02:39

US3172250

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:34:09

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 21:02:39

US3172250

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:02:39

US3172250

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:02:39

US3172250

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:34:09

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:02:39

US3172250

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:34:09

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 21:02:39

US3172250

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:34:09

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:02:39

US3172250

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:34:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:02:39

US3172250

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:34:09

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:02:39

US3172250

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:34:09

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:02:39

US3172250

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:34:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:02:39

US3172250

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:34:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:02:39

US3172250

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:34:09

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:02:39

US3172250

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:34:09

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:02:39

US3172250

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:34:09

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:02:39

US3172250

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:34:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:02:39

US3172250

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:34:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:02:39

US3172250

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:34:09

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:02:39

US3172250

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:34:09

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:02:39

US3172250

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:34:09

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:02:39

US3172250

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:34:09

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:02:39

US3172250

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:34:09

[None](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:02:39

US3172250

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:34:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered 'I'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:02:39

US3172250

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:34:09

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:02:39

US3172250

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:34:09

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:02:39

US3172250

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:34:09

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:02:39

US3172250

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:34:09

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:02:39

US3172250

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:34:09

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Apr 2021 21:02:39

US3172250

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:34:09

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Apr 2021 21:02:39

US3172250

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:34:09

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Hepatobiliary disorders, HLG: Hepatic and hepatobiliary disorders, HLT: Hepatobiliary signs and symptoms, PT: Hepatomegaly, LLT: Hepatomegaly - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 20:51:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 20:51:21
Data point term sent to Coder	System	06 Apr 2021 20:50:57
User entered 'hepatomegaly'	Jessie Downs (b) (4)	06 Apr 2021 20:50:06

US3172250

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:34:09

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:50:06

US3172250

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:34:09

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 19:55:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Apr 2021 19:55:08
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	16 Apr 2021 19:55:08
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Apr 2021 20:50:06
User entered empty.	Jessie Downs (b) (4)	06 Apr 2021 20:50:06

US3172250

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:34:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 19:55:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Apr 2021 19:55:08
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	16 Apr 2021 19:55:08
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Apr 2021 20:50:06
User entered empty.	Jessie Downs (b) (4)	06 Apr 2021 20:50:06

US3172250

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:34:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '05 Mar 2021'	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:50:06

US3172250

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:34:09

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:50:06

US3172250

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:34:09

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 20:50:06

US3172250

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:50:06

US3172250

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:50:06

US3172250

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:34:09

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:50:06

US3172250

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:34:09

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 20:50:06

US3172250

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:34:09

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:50:06

US3172250

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:34:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:50:06

US3172250

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:34:09

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:50:06

US3172250

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:34:09

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:50:06

US3172250

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:34:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:50:06

US3172250

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:34:09

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:50:06

US3172250

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:34:09

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:50:06

US3172250

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:34:09

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:50:06

US3172250

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:34:09

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:50:06

US3172250

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:34:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:50:06

US3172250

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:34:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:50:06

US3172250

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:34:09

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:50:06

US3172250

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:34:09

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:50:06

US3172250

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:34:09

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:50:06

US3172250

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:34:09

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:50:06

US3172250

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:34:09

None

Audit	User	Time (GMT)
User entered 'I'	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:50:06

US3172250

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:34:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:50:06

US3172250

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:34:09

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:50:06

US3172250

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:34:09

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:50:06

US3172250

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:34:09

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:50:06

US3172250

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:34:09

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:50:06

US3172250

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:34:09

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	06 Apr 2021 20:50:06

US3172250

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 15:34:09

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Apr 2021 20:50:06

US3172250

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:34:09

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Renal and urinary disorders, HLGT: Renal disorders (excl nephropathies), HLT: Renal failure and impairment, PT: Chronic kidney disease, LLT: Chronic kidney disease - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 20:53:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Apr 2021 20:53:25
Data point term sent to Coder	System	06 Apr 2021 20:52:59
User entered 'chronic kidney disease (CKD)'	Jessie Downs (b) (4)	06 Apr 2021 20:52:56

US3172250

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:34:09

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:52:56

US3172250

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:34:09

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:52:56

US3172250

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:34:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:52:56

US3172250

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:34:09

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Sep 2020'	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:52:56

US3172250

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:34:09

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:52:56

US3172250

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:34:09

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 20:52:56

US3172250

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:52:56

US3172250

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:52:56

US3172250

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:34:09

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:52:56

US3172250

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:34:09

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 20:52:56

US3172250

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:34:09

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:52:56

US3172250

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:34:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:52:56

US3172250

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:34:09

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:52:56

US3172250

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:34:09

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:52:56

US3172250

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:34:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:52:56

US3172250

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:34:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:52:56

US3172250

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:34:09

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:52:56

US3172250

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:34:09

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:52:56

US3172250

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:34:09

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:52:56

US3172250

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:34:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:52:56

US3172250

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:34:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:52:56

US3172250

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:34:09

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:52:56

US3172250

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:34:09

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:52:56

US3172250

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:34:09

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:52:56

US3172250

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:34:09

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Apr 2021 19:55:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Apr 2021 19:55:36
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Jessie Downs (b) (4)	16 Apr 2021 19:55:36
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Apr 2021 20:52:56
User entered empty.	Jessie Downs (b) (4)	06 Apr 2021 20:52:56

US3172250

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:34:09

[None](#)

Audit	User	Time (GMT)
User entered 'I'	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:52:56

US3172250

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:34:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:52:56

US3172250

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:34:09

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:52:56

US3172250

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:34:09

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:52:56

US3172250

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:34:09

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:52:56

US3172250

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:34:09

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	06 Apr 2021 20:52:56

US3172250

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:34:09

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	06 Apr 2021 20:52:56

US3172250

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 15:34:09

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	06 Apr 2021 20:52:56

US3172250

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:34:09

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:03:18
User entered 'USA-US118-2021-mRNA-1273-P301000008'	(b) (4), (b) (6)	19 Apr 2021 15:01:41

US3172250

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:34:09

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure congestive, LLT: Congestive cardiac failure aggravated - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Apr 2021 10:58:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Apr 2021 10:58:33
Data point term sent to Coder	System	16 Apr 2021 19:43:44
User entered 'acute exacerbation of chronic congestive heart failure'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 19:43:19

US3172250

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:34:09

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 19:43:19

US3172250

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:34:09

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 19:43:19

US3172250

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:34:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 19:43:19

US3172250

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:34:09

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '08 Feb 2021'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 19:43:19

US3172250

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:34:09

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 19:43:19

US3172250

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:34:09

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 19:43:19

US3172250

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 19:43:19

US3172250

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '16 Feb 2021'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 19:43:19

US3172250

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:34:09

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 19:43:19

US3172250

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:34:09

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 19:43:19

US3172250

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:34:09

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 19:43:19

US3172250

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:34:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 19:43:19

US3172250

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:34:09

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 19:43:19

US3172250

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:34:09

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 19:43:19

US3172250

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:34:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	16 Apr 2021 19:52:51
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).		16 Apr 2021 19:52:51
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	16 Apr 2021 19:43:19
User entered 'I'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 19:43:19

US3172250

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:34:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '08 Feb 2021' reason for change: Data Entry Error	Jessie Downs (b) (4)	16 Apr 2021 19:52:51
User entered empty.	Jessie Downs (b) (4)	16 Apr 2021 19:43:19

US3172250

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:34:09

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Feb 2021' reason for change: Data Entry Error	Jessie Downs (b) (4)	16 Apr 2021 19:52:51
User entered empty.	Jessie Downs (b) (4)	16 Apr 2021 19:43:19

US3172250

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:34:09

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 19:43:19

US3172250

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:34:09

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User closed query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	System	23 Apr 2021 17:25:19
Query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' answered by data change (Site from System).	System	23 Apr 2021 17:25:19
User entered '1' reason for change: Data Entry Error	Jessie Downs (b) (4)	23 Apr 2021 17:25:19
User opened query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	(b) (4) System	16 Apr 2021 19:43:19
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 19:43:19

US3172250

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:34:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 19:43:19

US3172250

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:34:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 19:43:19

US3172250

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:34:09

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 19:43:19

US3172250

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:34:09

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 19:43:19

US3172250

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:34:09

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 19:43:19

US3172250

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:34:09

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 19:43:19

US3172250

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:34:09

[None](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 19:43:19

US3172250

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:34:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered 'I'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 19:43:19

US3172250

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:34:09

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 19:43:19

US3172250

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:34:09

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 19:43:19

US3172250

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:34:09

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 19:43:19

US3172250

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:34:09

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 16:06:34
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)	03 May 2021 16:06:28
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 16:06:23
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Narrative was updated.' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	30 Apr 2021 19:19:52

US3172250

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:34:09

[Narrative](#)

Audit	User	Time (GMT)
User entered 'AFTER REVIEW OF MEDICAL RECORDS FROM LARKIN HOSPITAL A NEW TERM FROM SOB SAE WAS UPDATED TO ACUTE EXACERBATION OF CHRONIC CONGESTIVE HEART FAILURE. SUBJECT WITH MANIFESTATIONS OF SHORTNESS OF BREATH, CHEST PAIN, AND ACUTE PULMONARY EDEMA AND BILATERAL LOW EXTREMITIES EDEMA SIGNS AND SYMPTOMS. SUBJECT WAS ADMITTED TO PALMETTO HOSPITAL ON FEBRUARY 8, 2021 UNTIL FEBRUARY 10, 2021. RECORDS WILL BE REQUESTED. TWO DAYS LATER WAS ADMITTED TO LARKIN HOSPITAL AGAIN FOR ONGOING SYMPTOMS. SUBJECT DISCHARGED FROM LARKIN HOSPITAL ON FEBRUARY 16, 2021. MEDICAL HISTORY AND CONCOMITANT MEDICATION LOG WERE UPDATED. COVID-19 PCR TEST WAS PERFORMED 13FEB2021 COLLECTION RESULTS NEGATIVE. TROPONIN I WAS ALSO COLLECTED 13FEB2021. RESULTS 0.03 WITH A REFERENCE RANGE OF 0.06-0.29 NG/ML. ON 13FEB2021 THE FOLLOWING PROCEDURES WERE PERFORMED ON SUBJECT: XR CHEST (1VIEW) IMPRESSION: CARDIOMEGALY. COMPREHENSIVE 2D DOPPLER AND ECHOCARDIOGRAM SHOWED LVEF OF 10-15%. SUBJECT WAS DISCHARGED ON 16FEB2021 WITH ORDER FROM HOME HEALTH SERVICE AND TO CONTINUE UNDER PRIMARY CARE PHYSICIAN FOLLOW-UP.'	Jessie Downs (b) (4) (b) (4)	30 Apr 2021 19:19:46
reason for change: Data Entry Error		

US3172250

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:34:09

[Narrative](#)

Audit	User	Time (GMT)
User entered 'AFTER REVIEW OF MEDICAL RECORDS FROM LARKIN HOSPITAL A NEW TERM FROM SOB SAE WAS UPDATED TO ACUTE EXACERBATION OF CHRONIC CONGESTIVE HEART FAILURE. SUBJECT WITH MANIFESTATIONS OF SHORTNESS OF BREATH, CHEST PAIN, AND ACUTE PULMONARY EDEMA AND BILATERAL LOW EXTREMITIES EDEMA SIGNS AND SYMPTOMS. SUBJECT WAS ADMITTED TO PALMETTO HOSPITAL ON FEBRUARY 8, 2021 UNTIL FEBRUARY 10, 2021. RECORDS WILL BE REQUESTED. TWO DAYS LATER WAS ADMITTED TO LARKIN HOSPITAL AGAIN FOR ONGOING SYMPTOMS. SUBJECT DISCHARGED FROM LARKIN HOSPITAL ON FEBRUARY 16, 2021. MEDICAL HISTORY AND CONCOMITANT MEDICATION LOG WERE UPDATED. COVID-19 PCR TEST WAS PERFORMED 13FEB2021 COLLECTION RESULTS NEGATIVE. TROPONIN I WAS ALSO COLLECTED 13FEB2021. RESULTS 0.03 WITH A REFERENCE RANGE OF 0.06-0.29 NG/ML. ON 13FEB2021 THE FOLLOWING PROCEDURES WERE PERFORMED ON SUBJECT: XR CHEST (1VIEW) IMPRESSION: CARDIOMEGALY. COMPREHENSIVE 2D DOPPLER AND ECHOCARDIOGRAM SHOWED LVEF OF 10-15%. SUBJECT WAS DISCHARGED ON 16FEB2021 WITH ORDER FROM HOME HEALTH SERVICE AND TO CONTINUE UNDER PRIMARY CARE PHYSICIAN FOLLOW-UP.' reason for change: Data Entry Error	Jessie Downs (b) (4)	30 Apr 2021 19:18:30
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 'Narrative was updated.' (Site from Safety).	Jessie Downs (b) (4)	30 Apr 2021 19:16:56

PRODUCTION RELEASE (v12.003
EAB) (1725)

2642 of 4086

US3172250

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:34:09

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'Narrative was updated.' (Site from Safety).	Jessie Downs (b) (4)	30 Apr 2021 19:16:51
User entered 'AFTER REVIEW OF MEDICAL RECORDS FROM LARKIN HOSPITAL A NEW TERM FROM SOB SAE WAS UPDATED TO ACUTE EXACERBATION OF CHRONIC CONGESTIVE HEART FAILURE. SUBJECT WITH MANIFESTATIONS OF SHORTNESS OF BREATH, CHEST PAIN, AND ACUTE PULMONARY EDEMA AND BILATERAL LOW EXTREMITIES EDEMA SIGNS AND SYMPTOMS. SUBJECT WAS ADMITTED TO PALMETTO HOSPITAL ON FEBRUARY 8, 2021 UNTIL FEBRUARY 10, 2021. RECORDS WILL BE REQUESTED. TWO DAYS LATER WAS ADMITTED TO LARKIN HOSPITAL AGAIN FOR ONGOING SYMPTOMS. SUBJECT DISCHARGED FROM LARKIN HOSPITAL ON FEBRUARY 16, 2021. MEDICAL HISTORY AND CONCOMITANT MEDICATION LOG WERE UPDATED. COVID-19 PCR TEST WAS PERFORMED 13FEB2021 COLLECTION RESULTS NEGATIVE. TROPONIN I WAS ALSO COLLECTED 13FEB2021. RESULTS 0.03 WITH A REFERENCE RANGE OF 0.06-0.29 NG/ML. ON 13FEB2021 THE FOLLOWING PROCEDURES WERE PERFORMED ON SUBJECT: XR CHEST (1VIEW) IMPRESSION: CARDIOMEGALY. COMPREHENSIVE 2D DOPPLER AND ECHOCARDIOGRAM SHOWED LVEF OF 10-15%.' reason for change: Data Entry Error	Jessie Downs (b) (4)	30 Apr 2021 19:16:27
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 15:01:46

PRODUCTION RELEASE (v12.003
EAB) (1725)

2643 of 4086

US3172250

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:34:09

[Narrative](#)

Audit	User	Time (GMT)
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)	23 Apr 2021 15:01:38
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 15:01:30
User entered 'after review of medical records from Larkin hospital a new term from SOB SAE was updated to acute exacerbation of chronic congestive heart failure. subject with manifestations of shortness of breath, chest pain, and acute pulmonary edema and bilateral low extremities edema signs and symptoms. subject was admitted to palmetto hospital on February 8, 2021 until February 10, 2021. records will be requested. two days later was admitted to Larkin hospital again for ongoing symptoms. subject discharged from Larkin hospital on February 16, 2021. medical history and concomitant medication log were updated.' reason for change: Data Entry Error	Jessie Downs (b) (4)	16 Apr 2021 19:52:12
User entered empty.	Jessie Downs (b) (4)	16 Apr 2021 19:43:19

US3172250

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:34:09

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Apr 2021 19:43:19

US3172250

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:34:09

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Apr 2021 19:43:19

US3172250

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 15:34:09

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Apr 2021 19:43:19

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:34:09

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:07:08
DataPoint Un-verified.	(b) (4), (b) (6)	26 Apr 2021 14:27:31
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 14:27:15
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	20 Aug 2020 21:11:10

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:26:09
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
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)	20 Aug 2020 21:13:27
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	20 Aug 2020 21:13:27
User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	20 Aug 2020 21:12:08
User entered 'LISINOPRIL'	Jessie Downs (b) (4)	20 Aug 2020 21:12:03
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:26:09
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	20 Aug 2020 21:12:03
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:26:09
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'HYPERTENSION'	Jessie Downs (b) (4)	20 Aug 2020 21:12:03
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:26:09
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered '40'	Jessie Downs (b) (4)	20 Aug 2020 21:12:03
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:26:09
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'mg (mg)'	Jessie Downs (b) (4)	20 Aug 2020 21:12:03
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:26:09
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	20 Aug 2020 21:12:03
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:26:09
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'once daily (QD)'	Jessie Downs (b) (4)	20 Aug 2020 21:12:03
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:26:09
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	20 Aug 2020 21:12:03
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:26:09
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'Oral (ORAL)'	Jessie Downs (b) (4)	20 Aug 2020 21:12:03
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:26:09
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	20 Aug 2020 21:12:03
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:26:09
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:57:52
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 21:12:03
User entered 'UN UNK 2015'	Jessie Downs (b) (4)	20 Aug 2020 21:12:03
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:26:09
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	20 Aug 2020 21:12:03
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:26:09
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:55:57
	(b) (4)	
Signature has been broken.	Jessie Downs (b) (4)	02 Mar 2021 19:45:22
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	02 Mar 2021 19:45:22
	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	20 Aug 2020 21:12:03
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:26:09
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:55:57
	(b) (4)	
Signature has been broken.	Jessie Downs (b) (4)	02 Mar 2021 19:45:22
	(b) (4)	
User entered '16 Sep 2020' reason for change: Data Entry Error	Jessie Downs (b) (4)	02 Mar 2021 19:45:22
	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	20 Aug 2020 21:12:03
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:26:09
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	20 Aug 2020 21:12:03
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:26:09
User entered '1'	System	20 Aug 2020 21:12:03

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:26:09
User entered '1'	System	20 Aug 2020 21:12:03

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:26:09
User entered '804 (804)'	System	20 Aug 2020 21:12:03

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 21:15:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 21:15:20
Data point term sent to Coder User entered 'FUROSEMIDE'	System Jessie Downs (b) (4) (b) (4)	20 Aug 2020 21:14:13 20 Aug 2020 21:13:35

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	20 Aug 2020 21:13:35

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'HYPERTENSION'	Jessie Downs (b) (4) (b) (4)	20 Aug 2020 21:13:35

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered '40'	Jessie Downs (b) (4) (b) (4)	20 Aug 2020 21:13:35

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	20 Aug 2020 21:13:35

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Aug 2020 21:13:35

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'once daily (QD)'	Jessie Downs (b) (4) (b) (4)	20 Aug 2020 21:13:35

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Aug 2020 21:13:35

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	20 Aug 2020 21:13:35

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Aug 2020 21:13:35

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:59
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:57:52
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 21:13:35
User entered 'UN UNK 2015'	Jessie Downs (b) (4)	20 Aug 2020 21:13:35
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered '0'	Jessie Downs (b) (4) (b) (4)	20 Aug 2020 21:13:35

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:59
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:55:57
	(b) (4)	
Signature has been broken.	Jessie Downs (b) (4)	02 Mar 2021 19:45:45
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	02 Mar 2021 19:45:45
	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	20 Aug 2020 21:13:35
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:59
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:55:57
	(b) (4)	
Signature has been broken.	Jessie Downs (b) (4)	02 Mar 2021 19:45:45
	(b) (4)	
User entered 'un Aug 2020' reason for change: Data Entry Error	Jessie Downs (b) (4)	02 Mar 2021 19:45:45
	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	20 Aug 2020 21:13:35
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	20 Aug 2020 21:13:35

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:59
User entered '1'	System	20 Aug 2020 21:13:35

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:59
User entered '1'	System	20 Aug 2020 21:13:35

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:59
User entered '804 (804)'	System	20 Aug 2020 21:13:35

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:35:04
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: HEMODIALYTICS AND HEMOFILTRATES, ATC: HEMODIALYTICS, CONCENTRATES, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 22:37:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 22:37:57
Data point term sent to Coder	System	24 Nov 2020 20:08:10
User entered 'potassium chloride'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:07:17

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:35:04
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:07:17

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:35:04
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'chronic heart failure'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:07:17

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:35:04
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered '20'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:07:17

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:35:04
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 15:04:53
User entered 'Other (OTHER)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 15:04:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:07:17

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:35:04
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 15:04:53
User entered 'meq' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 15:04:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:07:17

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:35:04
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'once daily (QD)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:07:17

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:35:04
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:07:17

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:35:04
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:07:17

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:35:04
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:07:17

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:35:04
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'un Feb 2020'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:07:17

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:35:04
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered '0'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:07:17

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:35:04
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 15:03:11
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 15:03:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:07:17

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:35:04
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 15:03:11
User entered 'un Mar 2021' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 15:03:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:07:17

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:35:04
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:07:17

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:35:04
User entered '1'	System	24 Nov 2020 20:07:17

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:35:04
User entered '1'	System	24 Nov 2020 20:07:17

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:35:04
User entered '804 (804)'	System	24 Nov 2020 20:07:17

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), COMBINATIONS, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), OTHER COMBINATIONS, PRODUCT: SACUBITRIL VALSARTAN SODIUM HYDRATE, PRODUCTSYNONYM: ENTRESTO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 20:11:00
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 20:11:00
	(b) (4)	
Data point term sent to Coder	System	24 Nov 2020 20:10:16
User entered 'entresto'	Jessie Downs (b) (4)	24 Nov 2020 20:09:44
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:09:44

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'hypertension'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:09:44

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered '24/26'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:09:44

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:09:44

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:09:44

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'twice daily (BID)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:09:44

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:09:44

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:09:44

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:09:44

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:09

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'un Jun 2020'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:09:44

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered '0'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:09:44

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:09:44

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:09:44

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:09:44

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	24 Nov 2020 20:09:44

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 20:09:44

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Nov 2020 20:09:44

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: ANTIARRHYTHMICS, CLASS I AND III, ATC: ANTIARRHYTHMICS, CLASS III, PRODUCT: AMIODARONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 20:16:04
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 20:16:04
	(b) (4)	
Data point term sent to Coder	System	24 Nov 2020 20:15:25
User entered 'amiodarone'	Jessie Downs (b) (4)	24 Nov 2020 20:15:08
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:15:08

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'paroxysmal atrial fibrillation'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:15:08

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered '200'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:15:08

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:15:08

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:15:08

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'once daily (QD)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:15:08

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:09

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:15:08

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Nov 2020 20:15:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Nov 2020 20:15:21
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Jessie Downs (b) (4)	24 Nov 2020 20:15:21
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	24 Nov 2020 20:15:08
User entered empty.	Jessie Downs (b) (4)	24 Nov 2020 20:15:08
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:15:08

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:09

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'un UNK 2015'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:15:08

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered '0'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:15:08

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:15:08

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:15:08

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:15:08

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 20:15:08

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 20:15:08

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Nov 2020 20:15:08

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:57
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 20:23:00
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 20:23:00
	(b) (4)	
Data point term sent to Coder	System	24 Nov 2020 20:22:38
User entered 'eliquis'	Jessie Downs (b) (4)	24 Nov 2020 20:21:40
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:57
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	24 Nov 2020 20:21:40
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:57
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'anticoagulant atrial fibrillation'	Jessie Downs (b) (4)	24 Nov 2020 20:21:40
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:57
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered '5'	Jessie Downs (b) (4)	24 Nov 2020 20:21:40
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:57
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'mg (mg)'	Jessie Downs (b) (4)	24 Nov 2020 20:21:40
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:57
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	24 Nov 2020 20:21:40
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:57
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'twice daily (BID)'	Jessie Downs (b) (4)	24 Nov 2020 20:21:40
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:57
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	24 Nov 2020 20:21:40
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:57
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'Oral (ORAL)'	Jessie Downs (b) (4)	24 Nov 2020 20:21:40
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:57
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	24 Nov 2020 20:21:40
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:57
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'un UNK 2015'	Jessie Downs (b) (4)	24 Nov 2020 20:21:40
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:57
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	24 Nov 2020 20:21:40
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:57
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
Signature has been broken.	Jessie Downs (b) (4)	23 Apr 2021 15:13:57
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	23 Apr 2021 15:13:57
	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	24 Nov 2020 20:21:40
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:57
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
Signature has been broken.	Jessie Downs (b) (4)	23 Apr 2021 15:13:57
	(b) (4)	
User entered '12 Feb 2021' reason for change: Data Entry Error	Jessie Downs (b) (4)	23 Apr 2021 15:13:57
	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	24 Nov 2020 20:21:40
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:57
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	24 Nov 2020 20:21:40
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:57
User entered '2'	System	24 Nov 2020 20:21:40

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:57
User entered '1'	System	24 Nov 2020 20:21:40

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:57
User entered '804 (804)'	System	24 Nov 2020 20:21:40

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:58
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: BUMETANIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 20:28:01
	(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 Nov 2020 20:28:01
	(b) (4)	
Data point term sent to Coder	System	24 Nov 2020 20:26:42
User entered 'bumetanide'	Jessie Downs (b) (4)	24 Nov 2020 20:25:45
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:58
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	24 Nov 2020 20:25:45
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:58
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'chronic heart failure diuretic'	Jessie Downs (b) (4)	24 Nov 2020 20:25:45
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:58
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered '1'	Jessie Downs (b) (4)	24 Nov 2020 20:25:45
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:58
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'mg (mg)'	Jessie Downs (b) (4)	24 Nov 2020 20:25:45
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:58
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	24 Nov 2020 20:25:45
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:58
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'twice daily (BID)'	Jessie Downs (b) (4)	24 Nov 2020 20:25:45
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:58
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	24 Nov 2020 20:25:45
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:58
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'Oral (ORAL)'	Jessie Downs (b) (4)	24 Nov 2020 20:25:45
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:58
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	24 Nov 2020 20:25:45
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:58
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'un UNK 2008'	Jessie Downs (b) (4)	24 Nov 2020 20:25:45
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:58
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	24 Nov 2020 20:25:45
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:58
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
Signature has been broken.	Jessie Downs (b) (4)	23 Apr 2021 15:16:03
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	23 Apr 2021 15:16:03
	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	24 Nov 2020 20:25:45
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:58
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
Signature has been broken.	Jessie Downs (b) (4)	23 Apr 2021 15:16:03
	(b) (4)	
User entered '12 Feb 2021' reason for change: Data Entry Error	Jessie Downs (b) (4)	23 Apr 2021 15:16:03
	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	24 Nov 2020 20:25:45
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:58
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	24 Nov 2020 20:25:45
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:58
User entered '2'	System	24 Nov 2020 20:25:45

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:58
User entered '1'	System	24 Nov 2020 20:25:45

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:58
User entered '804 (804)'	System	24 Nov 2020 20:25:45

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:25:03
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 20:43:57
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 20:43:57
	(b) (4)	
Data point term sent to Coder	System	24 Nov 2020 20:43:01
User entered 'carvedilol'	Jessie Downs (b) (4)	24 Nov 2020 20:42:03
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:25:03
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	24 Nov 2020 20:42:03
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:25:03
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'hypertension'	Jessie Downs (b) (4)	24 Nov 2020 20:42:03
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:25:03
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered '3.125'	Jessie Downs (b) (4)	24 Nov 2020 20:42:03
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:25:03
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'mg (mg)'	Jessie Downs (b) (4)	24 Nov 2020 20:42:03
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:25:03
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	24 Nov 2020 20:42:03
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:25:03
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'twice daily (BID)'	Jessie Downs (b) (4)	24 Nov 2020 20:42:03
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:25:03
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	24 Nov 2020 20:42:03
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:25:03
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'Oral (ORAL)'	Jessie Downs (b) (4)	24 Nov 2020 20:42:03
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:25:03
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	24 Nov 2020 20:42:03
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:25:03
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
Signature has been broken.	Jessie Downs (b) (4)	23 Apr 2021 15:17:24
	(b) (4)	
User entered 'UN Feb 2020' reason for change: Data Entry Error	Jessie Downs (b) (4)	23 Apr 2021 15:17:24
	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'un UNK 2020'	Jessie Downs (b) (4)	24 Nov 2020 20:42:03
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:25:03
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	24 Nov 2020 20:42:03
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:25:03
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
Signature has been broken.	Jessie Downs (b) (4)	23 Apr 2021 15:17:24
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	23 Apr 2021 15:17:24
	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	24 Nov 2020 20:42:03
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:25:03
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
Signature has been broken.	Jessie Downs (b) (4)	23 Apr 2021 15:17:24
	(b) (4)	
User entered '12 Feb 2021' reason for change: Data Entry Error	Jessie Downs (b) (4)	23 Apr 2021 15:17:24
	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	24 Nov 2020 20:42:03
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:25:03
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	24 Nov 2020 20:42:03
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:25:03
User entered '2'	System	24 Nov 2020 20:42:03

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:25:03
User entered '1'	System	24 Nov 2020 20:42:03

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:25:03
User entered '804 (804)'	System	24 Nov 2020 20:42:03

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
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)	24 Nov 2020 20:49:06
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 20:49:06
	(b) (4)	
Data point term sent to Coder	System	24 Nov 2020 20:48:13
User entered 'gabapentin'	Jessie Downs (b) (4)	24 Nov 2020 20:47:34
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:47:34

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'chronic lower back pain'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:47:34

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered '300'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:47:34

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:47:34

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:47:34

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'three times daily (TID)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:47:34

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:47:34

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:47:34

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:47:34

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition of BACK PAIN (UN UNK 2018). Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 03:49:39
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition of BACK PAIN (UN UNK 2018). Please review and reconcile Con Med and MH start dates as appropriate. ' answered with 'Data was updated.' (Site from DM).	Jessie Downs (b) (4)	22 Dec 2020 20:43:41
User entered 'UN UNK 2018' reason for change: Data Entry Error	Jessie Downs (b) (4)	22 Dec 2020 20:43:19
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition of BACK PAIN (UN UNK 2018). Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 10:20:23
User entered 'un UNK 2016'	Jessie Downs (b) (4)	24 Nov 2020 20:47:34
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered '0'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:47:34

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:47:34

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:47:34

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:47:34

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	24 Nov 2020 20:47:34

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 20:47:34

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Nov 2020 20:47:34

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 20:51:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 20:51:29
Data point term sent to Coder	System	24 Nov 2020 20:50:18
User entered 'metformin'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:50:01

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:50:01

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'diabetes type ii'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:50:01

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered '500'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:50:01

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:50:01

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:50:01

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'twice daily (BID)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:50:01

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:50:01

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:50:01

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:50:01

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:09

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'un UNK 2015'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:50:01

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered '0'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:50:01

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:50:01

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:50:01

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 20:50:01

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	24 Nov 2020 20:50:01

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 20:50:01

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Nov 2020 20:50:01

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:34:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
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)	24 Nov 2020 21:01:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 21:01:57
Data point term sent to Coder	System	24 Nov 2020 21:00:32
User entered 'pantoprazole'	Jessie Downs (b) (4)	24 Nov 2020 21:00:04
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:00:04

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'Gastroesophageal reflux disease'	Jessie Downs (b) (4)	24 Nov 2020 21:00:04
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered '40'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:00:04

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:00:04

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:00:04

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'once daily (QD)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:00:04

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:34:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:00:04

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:00:04

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:00:04

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:34:09

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'un UNK 2015'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:00:04

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:34:09

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered '0'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:00:04

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:00:04

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:00:04

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:00:04

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 21:00:04

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 21:00:04

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Nov 2020 21:00:04

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:34:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 21:04:00
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 21:04:00
	(b) (4)	
Data point term sent to Coder	System	24 Nov 2020 21:02:42
User entered 'acetaminophen'	Jessie Downs (b) (4)	24 Nov 2020 21:02:10
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:02:10

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'chronic lower back pain'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:02:10

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered '650'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:02:10

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:02:10

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:02:10

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'as needed (PRN)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:02:10

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:34:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:02:10

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:02:10

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:02:10

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:34:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition of BACK PAIN (UN UNK 2018). Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 03:49:48
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition of BACK PAIN (UN UNK 2018). Please review and reconcile Con Med and MH start dates as appropriate. ' answered with 'Data was updated.' (Site from DM).	Jessie Downs (b) (4)	22 Dec 2020 20:46:26
User entered 'UN UNK 2018' reason for change:	Jessie Downs (b) (4)	22 Dec 2020 20:45:55
Data Entry Error	(b) (4)	
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition of BACK PAIN (UN UNK 2018). Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 10:19:37
User entered 'un UNK 2015'	Jessie Downs (b) (4)	24 Nov 2020 21:02:10
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:34:09

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered '0'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:02:10

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:02:10

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:02:10

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:02:10

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 21:02:10

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 21:02:10

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 21:02:10

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:34:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:08
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history of CHRONIC LOWER BACK PAIN worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 10:24:09
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history of CHRONIC LOWER BACK PAIN worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate.' answered with 'AE was removed.' (Site from DM).	Jessie Downs (b) (4)	28 Jan 2021 21:03:34
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history of CHRONIC LOWER BACK PAIN worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 16:48:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Nov 2020 21:07:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Nov 2020 21:07:57
Data point term sent to Coder	System	24 Nov 2020 21:06:55
User entered 'tramadol'	Jessie Downs (b) (4)	24 Nov 2020 21:06:41

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:08
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	24 Nov 2020 21:06:41
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:08
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'chronic lower back pain'	Jessie Downs (b) (4)	24 Nov 2020 21:06:41
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:08
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered '50'	Jessie Downs (b) (4)	24 Nov 2020 21:06:41
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:08
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'mg (mg)'	Jessie Downs (b) (4)	24 Nov 2020 21:06:41
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:08
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	24 Nov 2020 21:06:41
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:08
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'other (OTHER)'	Jessie Downs (b) (4)	24 Nov 2020 21:06:41
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:34:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:08
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'every 6 hours'	Jessie Downs (b) (4)	24 Nov 2020 21:06:41
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:08
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'Oral (ORAL)'	Jessie Downs (b) (4)	24 Nov 2020 21:06:41
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:08
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	24 Nov 2020 21:06:41
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:34:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:08
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered '12 Sep 2020'	Jessie Downs (b) (4)	24 Nov 2020 21:06:41
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:08
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	24 Nov 2020 21:06:41
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:08
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	24 Nov 2020 21:06:41
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:08
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered '19 Sep 2020'	Jessie Downs (b) (4)	24 Nov 2020 21:06:41
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:08
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	24 Nov 2020 21:06:41
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:08
User entered empty.	System	24 Nov 2020 21:06:41

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:08
User entered empty.	System	24 Nov 2020 21:06:41

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:08
User entered empty.	System	24 Nov 2020 21:06:41

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:34:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:10
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 15:34:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 15:34:45
Data point term sent to Coder Coding entries removed.	System Jessie Downs (b) (4) (b) (4)	23 Apr 2021 15:23:17 23 Apr 2021 15:22:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:41
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 22:09:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 22:09:55
Data point term sent to Coder Coding entries removed.	System Jessie Downs (b) (4) (b) (4)	22 Dec 2020 20:48:26 22 Dec 2020 20:48:17
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 21:46:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 21:46:02
Data point term sent to Coder User entered 'furosemide'	System Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:09:59 24 Nov 2020 21:09:15

PRODUCTION RELEASE (v12.003
EAB) (1725)

2883 of 4086

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:10
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	24 Nov 2020 21:09:15
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:10
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
Signature has been broken.	Jessie Downs (b) (4)	23 Apr 2021 15:22:45
User entered 'diuretic' reason for change: Data Entry Error	Jessie Downs (b) (4)	23 Apr 2021 15:22:45
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat instead of the drug class/action. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 03:49:55
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat instead of the drug class/action. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'Data was updated.' (Site from DM).	Jessie Downs (b) (4)	22 Dec 2020 20:48:36
User entered 'chronic heart failure' reason for change: Data Entry Error	Jessie Downs (b) (4)	22 Dec 2020 20:48:17
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat instead of the drug class/action. Please reconcile with AE eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 10:20:01
User entered 'diuretic'	Jessie Downs (b) (4)	24 Nov 2020 21:09:15

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:10
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
Signature has been broken.	Jessie Downs (b) (4)	23 Apr 2021 15:22:45
	(b) (4)	
User entered '40/4' reason for change: Data Entry Error	Jessie Downs (b) (4)	23 Apr 2021 15:22:45
	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered '40'	Jessie Downs (b) (4)	24 Nov 2020 21:09:15
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:10
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
Signature has been broken.	Jessie Downs (b) (4)	23 Apr 2021 15:22:45
	(b) (4)	
User entered 'Other (OTHER)' reason for change: Data Entry Error	Jessie Downs (b) (4)	23 Apr 2021 15:22:45
	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'mg (mg)'	Jessie Downs (b) (4)	24 Nov 2020 21:09:15
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:10
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
Signature has been broken.	Jessie Downs (b) (4)	23 Apr 2021 15:22:45
	(b) (4)	
User entered 'mg/ml' reason for change: Data Entry Error	Jessie Downs (b) (4)	23 Apr 2021 15:22:45
	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	24 Nov 2020 21:09:15
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:10
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'twice daily (BID)'	Jessie Downs (b) (4)	24 Nov 2020 21:09:15
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:34:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:10
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	24 Nov 2020 21:09:15
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:10
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Jessie Downs (b) (4)	24 Nov 2020 21:09:15
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:10
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	24 Nov 2020 21:09:15
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:34:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:10
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered '12 Sep 2020'	Jessie Downs (b) (4)	24 Nov 2020 21:09:15
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:10
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	24 Nov 2020 21:09:15
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:10
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	24 Nov 2020 21:09:15
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:10
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered '16 Sep 2020'	Jessie Downs (b) (4)	24 Nov 2020 21:09:15
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:10
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	24 Nov 2020 21:09:15
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:10
User entered '2'	System	24 Nov 2020 21:09:15

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:10
User entered '1'	System	24 Nov 2020 21:09:15

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:24:10
User entered '804 (804)'	System	24 Nov 2020 21:09:15

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:34:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:23:09
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: IRRIGATING SOLUTIONS, ATC: SALT SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Apr 2021 17:47:56
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Apr 2021 17:47:56
	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NACL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 22:20:04
	(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 Nov 2020 22:20:04
	(b) (4)	
Data point term sent to Coder	System	24 Nov 2020 21:13:03
User entered 'na cl 0.9% 10 ml'	Jessie Downs (b) (4)	24 Nov 2020 21:12:42
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:23:09
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	24 Nov 2020 21:12:42
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:23:09
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'flush iv catheter'	Jessie Downs (b) (4)	24 Nov 2020 21:12:42
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:23:09
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered '3'	Jessie Downs (b) (4)	24 Nov 2020 21:12:42
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:23:09
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'mL (mL)'	Jessie Downs (b) (4)	24 Nov 2020 21:12:42
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:23:09
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	24 Nov 2020 21:12:42
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:23:09
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'other (OTHER)'	Jessie Downs (b) (4)	24 Nov 2020 21:12:42
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:34:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:23:09
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'every 8 hours'	Jessie Downs (b) (4)	24 Nov 2020 21:12:42
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:23:09
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Jessie Downs (b) (4)	24 Nov 2020 21:12:42
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:23:09
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	24 Nov 2020 21:12:42
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:34:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:23:09
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered '12 Sep 2020'	Jessie Downs (b) (4)	24 Nov 2020 21:12:42
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:23:09
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	24 Nov 2020 21:12:42
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:23:09
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	24 Nov 2020 21:12:42
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:23:09
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered '16 Sep 2020'	Jessie Downs (b) (4)	24 Nov 2020 21:12:42
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:23:09
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	24 Nov 2020 21:12:42
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:23:09
User entered empty.	System	24 Nov 2020 21:12:42

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:23:09
User entered empty.	System	24 Nov 2020 21:12:42

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:23:09
User entered empty.	System	24 Nov 2020 21:12:42

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:34:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:23:11
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: IRRIGATING SOLUTIONS, ATC: SALT SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Apr 2021 15:35:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	(b) (4)	23 Apr 2021 15:35:51
Data point term sent to Coder	System	23 Apr 2021 15:24:18
Coding entries removed.	Jessie Downs (b) (4)	23 Apr 2021 15:23:49
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: IRRIGATING SOLUTIONS, ATC: SALT SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\202003.	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Apr 2021 17:47:57
User signature succeeded.	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NACL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Apr 2021 17:47:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	(b) (4)	
Data point term sent to Coder	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
User entered 'na cl 0.9% 10 ml'	(b) (4)	
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NACL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	24 Nov 2020 22:20:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	(b) (4)	
Data point term sent to Coder	Coder Import (b) (4)	24 Nov 2020 22:20:03
	(b) (4)	
	System	24 Nov 2020 21:15:06
	Jessie Downs (b) (4)	24 Nov 2020 21:14:16
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:23:11
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	24 Nov 2020 21:14:16
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:23:11
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
Signature has been broken.	Jessie Downs (b) (4)	23 Apr 2021 15:23:49
	(b) (4)	
User entered 'FLUSH iv CATHETER' reason for change: Data Entry Error	Jessie Downs (b) (4)	23 Apr 2021 15:23:49
	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'flush catheter'	Jessie Downs (b) (4)	24 Nov 2020 21:14:16
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:23:11
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered '3'	Jessie Downs (b) (4)	24 Nov 2020 21:14:16
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:23:11
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'mL (mL)'	Jessie Downs (b) (4)	24 Nov 2020 21:14:16
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:23:11
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	24 Nov 2020 21:14:16
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:23:11
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'other (OTHER)'	Jessie Downs (b) (4)	24 Nov 2020 21:14:16
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:34:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:23:11
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'every 5 minutes'	Jessie Downs (b) (4)	24 Nov 2020 21:14:16
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:23:11
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Jessie Downs (b) (4)	24 Nov 2020 21:14:16
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:23:11
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	24 Nov 2020 21:14:16
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:34:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:23:11
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered '12 Sep 2020'	Jessie Downs (b) (4)	24 Nov 2020 21:14:16
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:23:11
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	24 Nov 2020 21:14:16
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:23:11
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	24 Nov 2020 21:14:16
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:23:11
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered '14 Sep 2020'	Jessie Downs (b) (4)	24 Nov 2020 21:14:16
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:23:11
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:41
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	24 Nov 2020 21:14:16
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:23:11
User entered empty.	System	24 Nov 2020 21:14:16

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:23:11
User entered empty.	System	24 Nov 2020 21:14:16

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:23:11
User entered empty.	System	24 Nov 2020 21:14:16

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:34:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 04:48:49
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 04:48:49
	(b) (4)	
Data point term sent to Coder	System	24 Mar 2021 19:33:04
User entered 'oxycodone'	Jessie Downs (b) (4)	24 Mar 2021 19:32:20
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	24 Mar 2021 19:32:20

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered 'left sciatic exacerbation'	Jessie Downs (b) (4) (b) (4)	24 Mar 2021 19:32:20

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered '10/325'	Jessie Downs (b) (4) (b) (4)	24 Mar 2021 19:32:20

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	24 Mar 2021 19:32:20

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Mar 2021 19:32:20

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered 'as needed (PRN)'	Jessie Downs (b) (4) (b) (4)	24 Mar 2021 19:32:20

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:34:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Mar 2021 19:32:20

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	24 Mar 2021 19:32:20

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Mar 2021 19:32:20

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:34:09

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered 'un UNK 2018'	Jessie Downs (b) (4) (b) (4)	24 Mar 2021 19:32:20

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:34:09

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered '0'	Jessie Downs (b) (4) (b) (4)	24 Mar 2021 19:32:20

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	24 Mar 2021 19:32:20

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Mar 2021 19:32:20

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	24 Mar 2021 19:32:20

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 19:32:20

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 19:32:20

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 19:32:20

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:34:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:09:21
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
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)	06 Apr 2021 04:38:35
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 04:38:35
	(b) (4)	
Data point term sent to Coder	System	05 Apr 2021 21:07:55
User entered 'aspirin'	Jessie Downs (b) (4)	05 Apr 2021 21:07:28
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:09:21
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	05 Apr 2021 21:07:28
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:09:21
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'non st myocardia infarction'	Jessie Downs (b) (4)	05 Apr 2021 21:07:28
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:09:21
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '325'	Jessie Downs (b) (4)	05 Apr 2021 21:07:28
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:09:21
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'mg (mg)'	Jessie Downs (b) (4)	05 Apr 2021 21:07:28
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:09:21
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 21:07:28
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:09:21
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'once daily (QD)'	Jessie Downs (b) (4)	05 Apr 2021 21:07:28
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:34:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:09:21
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 21:07:28
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:09:21
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'Oral (ORAL)'	Jessie Downs (b) (4)	05 Apr 2021 21:07:28
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:09:21
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 21:07:28
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:34:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:09:21
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '26 Feb 2021'	Jessie Downs (b) (4)	05 Apr 2021 21:07:28
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:09:21
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	05 Apr 2021 21:07:28
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:09:21
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	05 Apr 2021 21:07:28
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:09:21
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '04 Mar 2021'	Jessie Downs (b) (4)	05 Apr 2021 21:07:28
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:09:21
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	05 Apr 2021 21:07:28
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:09:21
User entered '1'	System	05 Apr 2021 21:07:28

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:09:21
User entered '1'	System	05 Apr 2021 21:07:28

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:09:21
User entered '804 (804)'	System	05 Apr 2021 21:07:28

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:34:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
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)	05 Apr 2021 21:21:24
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 21:21:24
	(b) (4)	
Data point term sent to Coder	System	05 Apr 2021 21:08:56
User entered 'atorvastatin'	Jessie Downs (b) (4)	05 Apr 2021 21:08:24
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	05 Apr 2021 21:08:24
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'coronary artery disease'	Jessie Downs (b) (4)	05 Apr 2021 21:08:24
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '40'	Jessie Downs (b) (4)	05 Apr 2021 21:08:24
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'mg (mg)'	Jessie Downs (b) (4)	05 Apr 2021 21:08:24
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 21:08:24
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'once daily (QD)'	Jessie Downs (b) (4)	05 Apr 2021 21:08:24
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:34:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 21:08:24
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'Oral (ORAL)'	Jessie Downs (b) (4)	05 Apr 2021 21:08:24
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 21:08:24
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:34:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '26 Feb 2021'	Jessie Downs (b) (4)	05 Apr 2021 21:08:24
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	05 Apr 2021 21:08:24
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	05 Apr 2021 21:08:24
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '04 Mar 2021'	Jessie Downs (b) (4)	05 Apr 2021 21:08:24
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	05 Apr 2021 21:08:24
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:58
User entered '1'	System	05 Apr 2021 21:08:24

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:58
User entered '1'	System	05 Apr 2021 21:08:24

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:58
User entered '804 (804)'	System	05 Apr 2021 21:08:24

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:34:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:09:56
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 07:25:50
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 07:25:50
	(b) (4)	
Data point term sent to Coder	System	05 Apr 2021 21:09:58
User entered 'clopidogrel'	Jessie Downs (b) (4)	05 Apr 2021 21:09:50
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:09:56
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	05 Apr 2021 21:09:50
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:09:56
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'non st myocardial infarction'	Jessie Downs (b) (4)	05 Apr 2021 21:09:50
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:09:56
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '75'	Jessie Downs (b) (4)	05 Apr 2021 21:09:50
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:09:56
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'mg (mg)'	Jessie Downs (b) (4)	05 Apr 2021 21:09:50
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:09:56
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 21:09:50
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:09:56
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'once daily (QD)'	Jessie Downs (b) (4)	05 Apr 2021 21:09:50
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:34:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:09:56
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 21:09:50
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:09:56
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'Oral (ORAL)'	Jessie Downs (b) (4)	05 Apr 2021 21:09:50
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:09:56
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 21:09:50
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:34:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:09:56
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '26 Feb 2021'	Jessie Downs (b) (4)	05 Apr 2021 21:09:50
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:09:56
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	05 Apr 2021 21:09:50
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:09:56
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	05 Apr 2021 21:09:50
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:09:56
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '04 Mar 2021'	Jessie Downs (b) (4)	05 Apr 2021 21:09:50
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:09:56
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	05 Apr 2021 21:09:50
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:09:56
User entered '1'	System	05 Apr 2021 21:09:50

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:09:56
User entered '1'	System	05 Apr 2021 21:09:50

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:09:56
User entered '804 (804)'	System	05 Apr 2021 21:09:50

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:34:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:01
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 12:18:52
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 12:18:52
	(b) (4)	
Data point term sent to Coder	System	05 Apr 2021 21:12:04
User entered 'enoxaparin'	Jessie Downs (b) (4)	05 Apr 2021 21:11:51
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:01
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	05 Apr 2021 21:11:51
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:01
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'deep venous thrombosis prophylaxis (DVT)'	Jessie Downs (b) (4)	05 Apr 2021 21:11:51
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:01
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '110/0.73'	Jessie Downs (b) (4)	05 Apr 2021 21:11:51
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:01
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'Other (OTHER)'	Jessie Downs (b) (4)	05 Apr 2021 21:11:51
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:01
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'mg/ml'	Jessie Downs (b) (4)	05 Apr 2021 21:11:51
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:01
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'twice daily (BID)'	Jessie Downs (b) (4)	05 Apr 2021 21:11:51
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:34:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:01
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 21:11:51
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:01
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'Subcutaneous (SUBCUTANEOUS)'	Jessie Downs (b) (4)	05 Apr 2021 21:11:51
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:01
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 21:11:51
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:34:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:01
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '26 Feb 2021'	Jessie Downs (b) (4)	05 Apr 2021 21:11:51
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:01
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	05 Apr 2021 21:11:51
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:01
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	05 Apr 2021 21:11:51
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:01
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '04 Mar 2021'	Jessie Downs (b) (4)	05 Apr 2021 21:11:51
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:01
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	05 Apr 2021 21:11:51
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:01
User entered '2'	System	05 Apr 2021 21:11:51

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:01
User entered '1'	System	05 Apr 2021 21:11:51

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:01
User entered '804 (804)'	System	05 Apr 2021 21:11:51

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:34:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:19
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: PANCREATIC HORMONES, ATC: GLYCOGENOLYTIC HORMONES, ATC: GLYCOGENOLYTIC HORMONES, PRODUCT: GLUCAGON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 15:44:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	23 Apr 2021 15:44:00
Data point term sent to Coder	System	23 Apr 2021 15:27:19
Coding entries removed.	Jessie Downs (b) (4)	23 Apr 2021 15:27:00
User signature succeeded.	(b) (4)	22 Apr 2021 16:26:40
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: PANCREATIC HORMONES, ATC: GLYCOGENOLYTIC HORMONES, ATC: GLYCOGENOLYTIC HORMONES, PRODUCT: GLUCAGON - version WHODrug-Global-B3\\202003.	Mark Kutner (b) (4)	06 Apr 2021 12:20:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	06 Apr 2021 12:20:57
Data point term sent to Coder	System	05 Apr 2021 21:14:07
User entered 'glucagon'	Jessie Downs (b) (4)	05 Apr 2021 21:13:28

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:19
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	05 Apr 2021 21:13:28
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:19
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
Signature has been broken.	Jessie Downs (b) (4)	23 Apr 2021 15:27:00
	(b) (4)	
User entered 'severe HYPOGLYCEMIA PROPHYLAXES' reason for change: Data Entry Error	Jessie Downs (b) (4)	23 Apr 2021 15:27:00
	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'hypoglycemia prophylaxes'	Jessie Downs (b) (4)	05 Apr 2021 21:13:28
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:19
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '1'	Jessie Downs (b) (4)	05 Apr 2021 21:13:28
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:19
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'mg (mg)'	Jessie Downs (b) (4)	05 Apr 2021 21:13:28
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:19
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 21:13:28
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:19
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'as needed (PRN)'	Jessie Downs (b) (4)	05 Apr 2021 21:13:28
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:34:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:19
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 21:13:28
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:19
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'Intramuscular (INTRAMUSCULAR)'	Jessie Downs (b) (4)	05 Apr 2021 21:13:28
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:19
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 21:13:28
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:34:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:19
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '26 Feb 2021'	Jessie Downs (b) (4)	05 Apr 2021 21:13:28
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:19
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	05 Apr 2021 21:13:28
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:19
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	05 Apr 2021 21:13:28
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:19
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '04 Mar 2021'	Jessie Downs (b) (4)	05 Apr 2021 21:13:28
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:19
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	05 Apr 2021 21:13:28
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:19
User entered empty.	System	05 Apr 2021 21:13:28

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:19
User entered empty.	System	05 Apr 2021 21:13:28

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:19
User entered empty.	System	05 Apr 2021 21:13:28

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:34:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:48
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 04:00:47
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 04:00:47
	(b) (4)	
Data point term sent to Coder	System	05 Apr 2021 21:15:14
User entered 'rosuvastatin'	Jessie Downs (b) (4)	05 Apr 2021 21:14:48
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:48
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	05 Apr 2021 21:14:48
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:48
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'coronary artery disease dyslipidemia'	Jessie Downs (b) (4)	05 Apr 2021 21:14:48
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:48
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '10'	Jessie Downs (b) (4)	05 Apr 2021 21:14:48
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:48
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'mg (mg)'	Jessie Downs (b) (4)	05 Apr 2021 21:14:48
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:48
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 21:14:48
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:48
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'once daily (QD)'	Jessie Downs (b) (4)	05 Apr 2021 21:14:48
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:34:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:48
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 21:14:48
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:48
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'Oral (ORAL)'	Jessie Downs (b) (4)	05 Apr 2021 21:14:48
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:48
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 21:14:48
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:34:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:48
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '26 Feb 2021'	Jessie Downs (b) (4)	05 Apr 2021 21:14:48
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:48
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	05 Apr 2021 21:14:48
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:48
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	05 Apr 2021 21:14:48
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:48
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '04 Mar 2021'	Jessie Downs (b) (4)	05 Apr 2021 21:14:48
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:48
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	05 Apr 2021 21:14:48
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:48
User entered '1'	System	05 Apr 2021 21:14:48

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:48
User entered '1'	System	05 Apr 2021 21:14:48

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:08:48
User entered '804 (804)'	System	05 Apr 2021 21:14:48

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:34:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:14
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: POTASSIUM-SPARING AGENTS, ATC: ALDOSTERONE ANTAGONISTS, PRODUCT: SPIRONOLACTONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 03:58:43
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 03:58:43
	(b) (4)	
Data point term sent to Coder	System	05 Apr 2021 21:16:16
User entered 'spironolactone'	Jessie Downs (b) (4)	05 Apr 2021 21:15:46
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:14
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	05 Apr 2021 21:15:46
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:14
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'chronic heart failure'	Jessie Downs (b) (4)	05 Apr 2021 21:15:46
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:14
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '25'	Jessie Downs (b) (4)	05 Apr 2021 21:15:46
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:14
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'mg (mg)'	Jessie Downs (b) (4)	05 Apr 2021 21:15:46
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:14
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 21:15:46
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:14
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'once daily (QD)'	Jessie Downs (b) (4)	05 Apr 2021 21:15:46
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:34:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:14
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 21:15:46
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:14
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'Oral (ORAL)'	Jessie Downs (b) (4)	05 Apr 2021 21:15:46
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:14
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 21:15:46
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:34:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:14
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '26 Feb 2021'	Jessie Downs (b) (4)	05 Apr 2021 21:15:46
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:14
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	05 Apr 2021 21:15:46
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:14
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	05 Apr 2021 21:15:46
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:14
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
Signature has been broken.	Jessie Downs (b) (4)	23 Apr 2021 15:28:49
	(b) (4)	
User entered '25 Mar 2021' reason for change: Data Entry Error	Jessie Downs (b) (4)	23 Apr 2021 15:28:49
	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '04 Mar 2021'	Jessie Downs (b) (4)	05 Apr 2021 21:15:46
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:14
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	05 Apr 2021 21:15:46
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:14
User entered '1'	System	05 Apr 2021 21:15:46

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:14
User entered '1'	System	05 Apr 2021 21:15:46

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:14
User entered '804 (804)'	System	05 Apr 2021 21:15:46

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:34:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:16
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 21:30:20
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 21:30:20
	(b) (4)	
Data point term sent to Coder	System	05 Apr 2021 21:17:17
User entered 'acetaminophen'	Jessie Downs (b) (4)	05 Apr 2021 21:16:32
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:16
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	05 Apr 2021 21:16:32
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:16
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'left sciatica'	Jessie Downs (b) (4)	05 Apr 2021 21:16:32
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:16
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '650'	Jessie Downs (b) (4)	05 Apr 2021 21:16:32
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:16
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'mg (mg)'	Jessie Downs (b) (4)	05 Apr 2021 21:16:32
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:16
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 21:16:32
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:16
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'as needed (PRN)'	Jessie Downs (b) (4)	05 Apr 2021 21:16:32
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:34:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:16
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 21:16:32
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:16
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'Oral (ORAL)'	Jessie Downs (b) (4)	05 Apr 2021 21:16:32
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:16
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 21:16:32
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:34:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:16
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '26 Feb 2021'	Jessie Downs (b) (4)	05 Apr 2021 21:16:32
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:16
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	05 Apr 2021 21:16:32
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:16
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	05 Apr 2021 21:16:32
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:16
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '04 Mar 2021'	Jessie Downs (b) (4)	05 Apr 2021 21:16:32
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:16
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	05 Apr 2021 21:16:32
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:16
User entered empty.	System	05 Apr 2021 21:16:32

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:16
User entered empty.	System	05 Apr 2021 21:16:32

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:16
User entered empty.	System	05 Apr 2021 21:16:32

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:34:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:52
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ANTIADRENERGIC AGENTS, CENTRALLY ACTING, ATC: IMIDAZOLINE RECEPTOR AGONISTS, PRODUCT: CLONIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 07:24:45
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 07:24:45
	(b) (4)	
Data point term sent to Coder	System	05 Apr 2021 21:18:20
User entered 'clonidine'	Jessie Downs (b) (4)	05 Apr 2021 21:17:37
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:52
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	05 Apr 2021 21:17:37
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:52
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'hypertension emergency'	Jessie Downs (b) (4)	05 Apr 2021 21:17:37
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:52
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '0.1'	Jessie Downs (b) (4)	05 Apr 2021 21:17:37
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:52
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'mg (mg)'	Jessie Downs (b) (4)	05 Apr 2021 21:17:37
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:52
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 21:17:37
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:52
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'as needed (PRN)'	Jessie Downs (b) (4)	05 Apr 2021 21:17:37
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:34:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:52
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 21:17:37
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:52
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'Oral (ORAL)'	Jessie Downs (b) (4)	05 Apr 2021 21:17:37
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:52
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 21:17:37
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:34:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:52
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '26 Feb 2021'	Jessie Downs (b) (4)	05 Apr 2021 21:17:37
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:52
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	05 Apr 2021 21:17:37
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:52
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	05 Apr 2021 21:17:37
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:52
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '04 Mar 2021'	Jessie Downs (b) (4)	05 Apr 2021 21:17:37
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:52
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	05 Apr 2021 21:17:37
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:52
User entered empty.	System	05 Apr 2021 21:17:37

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:52
User entered empty.	System	05 Apr 2021 21:17:37

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:52
User entered empty.	System	05 Apr 2021 21:17:37

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:34:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:54
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS FOR PARENTERAL NUTRITION, PRODUCT: GLUCOSE, PRODUCTSYNONYM: DEXTROSE 10% - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 12:17:00
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 12:17:00
	(b) (4)	
Data point term sent to Coder	System	05 Apr 2021 21:19:21
User entered 'dextrose 10%'	Jessie Downs (b) (4)	05 Apr 2021 21:18:56
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:54
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	05 Apr 2021 21:18:56
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:54
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'severe hypoglycemia prophylaxis'	Jessie Downs (b) (4)	05 Apr 2021 21:18:56
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:54
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '250'	Jessie Downs (b) (4)	05 Apr 2021 21:18:56
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:54
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'mL (mL)'	Jessie Downs (b) (4)	05 Apr 2021 21:18:56
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:54
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 21:18:56
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:54
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'as needed (PRN)'	Jessie Downs (b) (4)	05 Apr 2021 21:18:56
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:34:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:54
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 21:18:56
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:54
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Jessie Downs (b) (4)	05 Apr 2021 21:18:56
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:54
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 21:18:56
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:34:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:54
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '26 Feb 2021'	Jessie Downs (b) (4)	05 Apr 2021 21:18:56
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:54
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	05 Apr 2021 21:18:56
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:54
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	05 Apr 2021 21:18:56
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:54
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '04 Mar 2021'	Jessie Downs (b) (4)	05 Apr 2021 21:18:56
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:54
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	05 Apr 2021 21:18:56
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:54
User entered empty.	System	05 Apr 2021 21:18:56

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:54
User entered empty.	System	05 Apr 2021 21:18:56

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:54
User entered empty.	System	05 Apr 2021 21:18:56

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:34:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS FOR PARENTERAL NUTRITION, PRODUCT: GLUCOSE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 12:20:57
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 12:20:57
	(b) (4)	
Data point term sent to Coder	System	05 Apr 2021 21:20:22
User entered 'glucose (D50 syringe)'	Jessie Downs (b) (4)	05 Apr 2021 21:20:08
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	05 Apr 2021 21:20:08
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'severe hypoglycemia prophylaxis'	Jessie Downs (b) (4)	05 Apr 2021 21:20:08
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '159/50'	Jessie Downs (b) (4)	05 Apr 2021 21:20:08
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'mL (mL)'	Jessie Downs (b) (4)	05 Apr 2021 21:20:08
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 21:20:08
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'as needed (PRN)'	Jessie Downs (b) (4)	05 Apr 2021 21:20:08
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:34:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 21:20:08
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Jessie Downs (b) (4)	05 Apr 2021 21:20:08
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 21:20:08
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:34:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '26 Feb 2021'	Jessie Downs (b) (4)	05 Apr 2021 21:20:08
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	05 Apr 2021 21:20:08
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	05 Apr 2021 21:20:08
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '04 Mar 2021'	Jessie Downs (b) (4)	05 Apr 2021 21:20:08
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:58
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	05 Apr 2021 21:20:08
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:58
User entered empty.	System	05 Apr 2021 21:20:08

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:58
User entered empty.	System	05 Apr 2021 21:20:08

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:11:58
User entered empty.	System	05 Apr 2021 21:20:08

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:34:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:31
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 12:22:54
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 12:22:54
	(b) (4)	
Data point term sent to Coder	System	05 Apr 2021 21:21:31
User entered 'hydromorphone'	Jessie Downs (b) (4)	05 Apr 2021 21:21:25
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:31
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	05 Apr 2021 21:21:25
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:31
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'chest pain / sciatica'	Jessie Downs (b) (4)	05 Apr 2021 21:21:25
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:31
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '0.5/0.5'	Jessie Downs (b) (4)	05 Apr 2021 21:21:25
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:31
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'Other (OTHER)'	Jessie Downs (b) (4)	05 Apr 2021 21:21:25
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:31
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'mg/ml'	Jessie Downs (b) (4)	05 Apr 2021 21:21:25
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:31
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'as needed (PRN)'	Jessie Downs (b) (4)	05 Apr 2021 21:21:25
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:34:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:31
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 21:21:25
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:31
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Jessie Downs (b) (4)	05 Apr 2021 21:21:25
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:31
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 21:21:25
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:34:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:31
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '26 Feb 2021'	Jessie Downs (b) (4)	05 Apr 2021 21:21:25
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:31
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	05 Apr 2021 21:21:25
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:31
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	05 Apr 2021 21:21:25
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:31
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '04 Mar 2021'	Jessie Downs (b) (4)	05 Apr 2021 21:21:25
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:31
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	05 Apr 2021 21:21:25
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:31
User entered empty.	System	05 Apr 2021 21:21:25

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:31
User entered empty.	System	05 Apr 2021 21:21:25

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:31
User entered empty.	System	05 Apr 2021 21:21:25

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:34:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:34
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
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, PRODUCTSYNONYM: INSULIN, REGULAR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 12:25:54
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 12:25:54
	(b) (4)	
Data point term sent to Coder	System	05 Apr 2021 21:22:52
User entered 'insulin regular'	Jessie Downs (b) (4)	05 Apr 2021 21:22:50
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:34
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	05 Apr 2021 21:22:50
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:34
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'diabetes mellitus'	Jessie Downs (b) (4)	05 Apr 2021 21:22:50
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:34
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	06 Apr 2021 13:19:06
Query 'Data is required. Please complete.' answered with 'sliding scale ' (Site from System).	Jessie Downs (b) (4)	05 Apr 2021 21:23:01
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 21:22:50
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 21:22:50
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:34
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	06 Apr 2021 13:19:09
Query 'Data is required. Please complete.' answered with 'sliding scale ' (Site from System).	Jessie Downs (b) (4)	05 Apr 2021 21:23:05
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	05 Apr 2021 21:22:50
	Jessie Downs (b) (4)	05 Apr 2021 21:22:50
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:34
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 21:22:50
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:34
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'as needed (PRN)'	Jessie Downs (b) (4)	05 Apr 2021 21:22:50
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:34:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:34
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 21:22:50
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:34
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'Subcutaneous (SUBCUTANEOUS)'	Jessie Downs (b) (4)	05 Apr 2021 21:22:50
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:34
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 21:22:50
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:34:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:34
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '26 Feb 2021'	Jessie Downs (b) (4)	05 Apr 2021 21:22:50
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:34
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	05 Apr 2021 21:22:50
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:34
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	05 Apr 2021 21:22:50
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:34
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '04 Mar 2021'	Jessie Downs (b) (4)	05 Apr 2021 21:22:50
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:34
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	05 Apr 2021 21:22:50
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:34
User entered empty.	System	05 Apr 2021 21:22:50

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:34
User entered empty.	System	05 Apr 2021 21:22:50

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:34
User entered empty.	System	05 Apr 2021 21:22:50

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:34:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:39
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 12:27:55
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 12:27:55
	(b) (4)	
Data point term sent to Coder	System	05 Apr 2021 21:24:55
User entered 'ketorolac'	Jessie Downs (b) (4)	05 Apr 2021 21:24:07
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:39
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	05 Apr 2021 21:24:07
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:39
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'sciatica'	Jessie Downs (b) (4)	05 Apr 2021 21:24:07
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:39
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '15'	Jessie Downs (b) (4)	05 Apr 2021 21:24:07
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:39
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'mg (mg)'	Jessie Downs (b) (4)	05 Apr 2021 21:24:07
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:39
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 21:24:07
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:39
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'as needed (PRN)'	Jessie Downs (b) (4)	05 Apr 2021 21:24:07
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:34:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:39
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 21:24:07
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:39
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'Subcutaneous (SUBCUTANEOUS)'	Jessie Downs (b) (4)	05 Apr 2021 21:24:07
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:39
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 21:24:07
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:34:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:39
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '26 Feb 2021'	Jessie Downs (b) (4)	05 Apr 2021 21:24:07
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:39
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	05 Apr 2021 21:24:07
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:39
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	05 Apr 2021 21:24:07
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:39
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '04 Mar 2021'	Jessie Downs (b) (4)	05 Apr 2021 21:24:07
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:39
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	05 Apr 2021 21:24:07
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:39
User entered empty.	System	05 Apr 2021 21:24:07

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:39
User entered empty.	System	05 Apr 2021 21:24:07

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:12:39
User entered empty.	System	05 Apr 2021 21:24:07

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:34:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:52
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: LORAZEPAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 21:38:15
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 21:38:15
	(b) (4)	
Data point term sent to Coder	System	05 Apr 2021 21:25:57
User entered 'lorazepam'	Jessie Downs (b) (4)	05 Apr 2021 21:25:06
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:52
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	05 Apr 2021 21:25:06
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:52
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'anxiety'	Jessie Downs (b) (4)	05 Apr 2021 21:25:06
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:52
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '1'	Jessie Downs (b) (4)	05 Apr 2021 21:25:06
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:52
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'mg (mg)'	Jessie Downs (b) (4)	05 Apr 2021 21:25:06
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:52
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 21:25:06
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:52
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'as needed (PRN)'	Jessie Downs (b) (4)	05 Apr 2021 21:25:06
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:34:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:52
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 21:25:06
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:52
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'Oral (ORAL)'	Jessie Downs (b) (4)	05 Apr 2021 21:25:06
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:52
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 21:25:06
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:34:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:52
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '26 Feb 2021'	Jessie Downs (b) (4)	05 Apr 2021 21:25:06
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:52
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	05 Apr 2021 21:25:06
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:52
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	05 Apr 2021 21:25:06
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:52
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '04 Mar 2021'	Jessie Downs (b) (4)	05 Apr 2021 21:25:06
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:52
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	05 Apr 2021 21:25:06
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:52
User entered empty.	System	05 Apr 2021 21:25:06

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:52
User entered empty.	System	05 Apr 2021 21:25:06

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:52
User entered empty.	System	05 Apr 2021 21:25:06

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:34:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:19
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: GLYCERYL TRINITRATE, PRODUCTSYNONYM: NITROGLYCERIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 21:40:54
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 21:40:54
	(b) (4)	
Data point term sent to Coder User entered 'nitroglycerin'	System	05 Apr 2021 21:28:01
	Jessie Downs (b) (4)	05 Apr 2021 21:27:16
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:19
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	05 Apr 2021 21:27:16
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:19
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'chest pain'	Jessie Downs (b) (4)	05 Apr 2021 21:27:16
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:19
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '0.4'	Jessie Downs (b) (4)	05 Apr 2021 21:27:16
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:19
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'mg (mg)'	Jessie Downs (b) (4)	05 Apr 2021 21:27:16
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:19
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 21:27:16
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:19
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'as needed (PRN)'	Jessie Downs (b) (4)	05 Apr 2021 21:27:16
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:34:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:19
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 21:27:16
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:19
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'Oral (ORAL)'	Jessie Downs (b) (4)	05 Apr 2021 21:27:16
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:19
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 21:27:16
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:34:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:19
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '26 Feb 2021'	Jessie Downs (b) (4)	05 Apr 2021 21:27:16
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:19
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	05 Apr 2021 21:27:16
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:19
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	05 Apr 2021 21:27:16
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:19
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '04 Mar 2021'	Jessie Downs (b) (4)	05 Apr 2021 21:27:16
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:19
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	05 Apr 2021 21:27:16
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:19
User entered empty.	System	05 Apr 2021 21:27:16

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:19
User entered empty.	System	05 Apr 2021 21:27:16

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:07:19
User entered empty.	System	05 Apr 2021 21:27:16

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:34:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:32
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 04:12:49
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Apr 2021 04:12:49
	(b) (4)	
Data point term sent to Coder	System	05 Apr 2021 21:29:01
User entered 'ondansetron'	Jessie Downs (b) (4)	05 Apr 2021 21:28:27
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:32
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	05 Apr 2021 21:28:27
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:32
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'emesis prophylaxis'	Jessie Downs (b) (4)	05 Apr 2021 21:28:27
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:32
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '4/2'	Jessie Downs (b) (4)	05 Apr 2021 21:28:27
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:32
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'Other (OTHER)'	Jessie Downs (b) (4)	05 Apr 2021 21:28:27
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:32
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'mg/ml'	Jessie Downs (b) (4)	05 Apr 2021 21:28:27
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:32
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'as needed (PRN)'	Jessie Downs (b) (4)	05 Apr 2021 21:28:27
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:34:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:32
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 21:28:27
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:32
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Jessie Downs (b) (4)	05 Apr 2021 21:28:27
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:32
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 21:28:27
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:34:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:32
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '26 Feb 2021'	Jessie Downs (b) (4)	05 Apr 2021 21:28:27
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:32
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	05 Apr 2021 21:28:27
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:32
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	05 Apr 2021 21:28:27
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:32
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '04 Mar 2021'	Jessie Downs (b) (4)	05 Apr 2021 21:28:27
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:32
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	05 Apr 2021 21:28:27
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:32
User entered empty.	System	05 Apr 2021 21:28:27

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:32
User entered empty.	System	05 Apr 2021 21:28:27

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:32
User entered empty.	System	05 Apr 2021 21:28:27

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:34:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:35
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 21:42:51
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 21:42:51
	(b) (4)	
Data point term sent to Coder	System	05 Apr 2021 21:30:05
User entered 'docusate'	Jessie Downs (b) (4)	05 Apr 2021 21:29:17
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:35
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	05 Apr 2021 21:29:17
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:35
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'constipation prophylaxis'	Jessie Downs (b) (4)	05 Apr 2021 21:29:17
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:35
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '100'	Jessie Downs (b) (4)	05 Apr 2021 21:29:17
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:35
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'mg (mg)'	Jessie Downs (b) (4)	05 Apr 2021 21:29:17
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:35
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 21:29:17
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:35
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'as needed (PRN)'	Jessie Downs (b) (4)	05 Apr 2021 21:29:17
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:34:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:35
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 21:29:17
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:35
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'Oral (ORAL)'	Jessie Downs (b) (4)	05 Apr 2021 21:29:17
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:35
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 21:29:17
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:34:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:35
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '26 Feb 2021'	Jessie Downs (b) (4)	05 Apr 2021 21:29:17
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:35
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	05 Apr 2021 21:29:17
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:35
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
Signature has been broken.	Jessie Downs (b) (4)	23 Apr 2021 15:34:20
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	23 Apr 2021 15:34:20
	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	05 Apr 2021 21:29:17
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:35
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
Signature has been broken.	Jessie Downs (b) (4)	23 Apr 2021 15:34:20
	(b) (4)	
User entered '04 Mar 2021' reason for change: Data Entry Error	Jessie Downs (b) (4)	23 Apr 2021 15:34:20
	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	05 Apr 2021 21:29:17
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:35
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	05 Apr 2021 21:29:17
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:35
User entered empty.	System	05 Apr 2021 21:29:17

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:35
User entered empty.	System	05 Apr 2021 21:29:17

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:10:35
User entered empty.	System	05 Apr 2021 21:29:17

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:34:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
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, PRODUCTSYNONYM: FERROUS SULPHATE [FERROUS SULFATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 21:42:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 21:42:51
Data point term sent to Coder	System	05 Apr 2021 21:30:05
User entered 'ferrous sulphate'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:30:04

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:30:04

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered 'anemia'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:30:04

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered '325'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:30:04

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:30:04

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:30:04

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered 'once daily (QD)'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:30:04

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:34:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:30:04

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:30:04

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:30:04

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:34:09

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered '27 Mar 2021'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:30:04

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered '0'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:30:04

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:30:04

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:30:04

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	05 Apr 2021 21:30:04

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 21:30:04

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 21:30:04

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Apr 2021 21:30:04

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:34:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:03
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: BUMETANIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 15:40:53
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 15:40:53
	(b) (4)	
Data point term sent to Coder	System	23 Apr 2021 15:37:38
User entered 'Bumetadine'	Jessie Downs (b) (4)	23 Apr 2021 15:37:24
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:03
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	23 Apr 2021 15:37:24
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:03
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'chronic heart failure exacerbation'	Jessie Downs (b) (4)	23 Apr 2021 15:37:24
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:03
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '2'	Jessie Downs (b) (4)	23 Apr 2021 15:37:24
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:03
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'mg (mg)'	Jessie Downs (b) (4)	23 Apr 2021 15:37:24
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:03
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Apr 2021 15:37:24
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:03
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'once daily (QD)'	Jessie Downs (b) (4)	23 Apr 2021 15:37:24
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:34:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:03
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Apr 2021 15:37:24
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:03
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'Oral (ORAL)'	Jessie Downs (b) (4)	23 Apr 2021 15:37:24
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:03
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Apr 2021 15:37:24
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:34:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:03
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '13 Feb 2021'	Jessie Downs (b) (4)	23 Apr 2021 15:37:24
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:03
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	23 Apr 2021 15:37:24
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:03
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	23 Apr 2021 15:37:24
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:03
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '13 Feb 2021'	Jessie Downs (b) (4)	23 Apr 2021 15:37:24
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:03
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	23 Apr 2021 15:37:24
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:03
User entered '1'	System	23 Apr 2021 15:37:24

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:03
User entered '1'	System	23 Apr 2021 15:37:24

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:03
User entered '804 (804)'	System	23 Apr 2021 15:37:24

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:34:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:10
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: BUMETANIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 15:41:57
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 15:41:57
	(b) (4)	
Data point term sent to Coder	System	23 Apr 2021 15:39:39
User entered 'bumetanide'	Jessie Downs (b) (4)	23 Apr 2021 15:39:07
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:10
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	23 Apr 2021 15:39:07
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:10
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'chronic heart failure exacerbation'	Jessie Downs (b) (4)	23 Apr 2021 15:39:07
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:10
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '2'	Jessie Downs (b) (4)	23 Apr 2021 15:39:07
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:10
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'mg (mg)'	Jessie Downs (b) (4)	23 Apr 2021 15:39:07
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:10
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Apr 2021 15:39:07
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:10
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'twice daily (BID)'	Jessie Downs (b) (4)	23 Apr 2021 15:39:07
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:34:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:10
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Apr 2021 15:39:07
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:10
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Jessie Downs (b) (4)	23 Apr 2021 15:39:07
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:10
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Apr 2021 15:39:07
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:34:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:10
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '13 Feb 2021'	Jessie Downs (b) (4)	23 Apr 2021 15:39:07
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:10
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	23 Apr 2021 15:39:07
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:10
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	23 Apr 2021 15:39:07
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:10
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '16 Feb 2021'	Jessie Downs (b) (4)	23 Apr 2021 15:39:07
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:10
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	23 Apr 2021 15:39:07
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:10
User entered '2'	System	23 Apr 2021 15:39:07

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:10
User entered '1'	System	23 Apr 2021 15:39:07

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:20:10
User entered '804 (804)'	System	23 Apr 2021 15:39:07

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:34:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:23
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 15:41:57
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 15:41:57
	(b) (4)	
Data point term sent to Coder	System	23 Apr 2021 15:40:40
User entered 'carvedilol'	Jessie Downs (b) (4)	23 Apr 2021 15:40:18
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:23
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	23 Apr 2021 15:40:18
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:23
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'hypertension'	Jessie Downs (b) (4)	23 Apr 2021 15:40:18
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:23
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '25'	Jessie Downs (b) (4)	23 Apr 2021 15:40:18
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:23
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'mg (mg)'	Jessie Downs (b) (4)	23 Apr 2021 15:40:18
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:23
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Apr 2021 15:40:18
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:23
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'once daily (QD)'	Jessie Downs (b) (4)	23 Apr 2021 15:40:18
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:34:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:23
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Apr 2021 15:40:18
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:23
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'Oral (ORAL)'	Jessie Downs (b) (4)	23 Apr 2021 15:40:18
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:23
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Apr 2021 15:40:18
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:34:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:23
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '13 Feb 2021'	Jessie Downs (b) (4)	23 Apr 2021 15:40:18
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:23
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	23 Apr 2021 15:40:18
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:23
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	23 Apr 2021 15:40:18
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:23
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '13 Feb 2021'	Jessie Downs (b) (4)	23 Apr 2021 15:40:18
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:23
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	23 Apr 2021 15:40:18
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:23
User entered '1'	System	23 Apr 2021 15:40:18

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:23
User entered '1'	System	23 Apr 2021 15:40:18

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:23
User entered '804 (804)'	System	23 Apr 2021 15:40:18

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:34:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:25
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 15:44:00
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 15:44:00
	(b) (4)	
Data point term sent to Coder	System	23 Apr 2021 15:42:42
User entered 'carvedilol'	Jessie Downs (b) (4)	23 Apr 2021 15:42:12
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:25
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	23 Apr 2021 15:42:12
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:25
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'hypertension'	Jessie Downs (b) (4)	23 Apr 2021 15:42:12
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:25
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '6.25'	Jessie Downs (b) (4)	23 Apr 2021 15:42:12
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:25
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'mg (mg)'	Jessie Downs (b) (4)	23 Apr 2021 15:42:12
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:25
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Apr 2021 15:42:12
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:25
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'twice daily (BID)'	Jessie Downs (b) (4)	23 Apr 2021 15:42:12
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:34:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:25
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Apr 2021 15:42:12
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:25
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'Oral (ORAL)'	Jessie Downs (b) (4)	23 Apr 2021 15:42:12
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:25
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Apr 2021 15:42:12
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:34:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:25
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '13 Feb 2021'	Jessie Downs (b) (4)	23 Apr 2021 15:42:12
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:25
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	23 Apr 2021 15:42:12
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:25
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	23 Apr 2021 15:42:12
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:25
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '13 Feb 2021'	Jessie Downs (b) (4)	23 Apr 2021 15:42:12
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:25
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	23 Apr 2021 15:42:12
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:25
User entered '2'	System	23 Apr 2021 15:42:12

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:25
User entered '1'	System	23 Apr 2021 15:42:12

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:19:25
User entered '804 (804)'	System	23 Apr 2021 15:42:12

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:34:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:22:06
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 15:44:46
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 15:44:46
	(b) (4)	
Data point term sent to Coder	System	23 Apr 2021 15:43:43
User entered 'carvedilol'	Jessie Downs (b) (4)	23 Apr 2021 15:43:39
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:22:06
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	23 Apr 2021 15:43:39
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:22:06
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'hypertension'	Jessie Downs (b) (4)	23 Apr 2021 15:43:39
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:22:06
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '12.5'	Jessie Downs (b) (4)	23 Apr 2021 15:43:39
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:22:06
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'mg (mg)'	Jessie Downs (b) (4)	23 Apr 2021 15:43:39
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:22:06
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Apr 2021 15:43:39
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:22:06
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'twice daily (BID)'	Jessie Downs (b) (4)	23 Apr 2021 15:43:39
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:34:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:22:06
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Apr 2021 15:43:39
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:22:06
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'Oral (ORAL)'	Jessie Downs (b) (4)	23 Apr 2021 15:43:39
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:22:06
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Apr 2021 15:43:39
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:34:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:22:06
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '13 Feb 2021'	Jessie Downs (b) (4)	23 Apr 2021 15:43:39
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:22:06
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	23 Apr 2021 15:43:39
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:22:06
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	23 Apr 2021 15:43:39
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:22:06
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '16 Feb 2021'	Jessie Downs (b) (4)	23 Apr 2021 15:43:39
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:22:06
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	23 Apr 2021 15:43:39
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:22:06
User entered '2'	System	23 Apr 2021 15:43:39

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:22:06
User entered '1'	System	23 Apr 2021 15:43:39

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:22:06
User entered '804 (804)'	System	23 Apr 2021 15:43:39

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:34:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 15:46:52
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 15:46:52
	(b) (4)	
Data point term sent to Coder	System	23 Apr 2021 15:45:44
User entered 'carvedilol'	Jessie Downs (b) (4)	23 Apr 2021 15:45:04
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 15:45:04

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'hypertension'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 15:45:04

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered '3.125'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 15:45:04

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Apr 2021 15:53:30
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Apr 2021 15:53:30
User entered 'mg (mg)' reason for change: Data Entry Error	Jessie Downs (b) (4)	23 Apr 2021 15:53:30
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Apr 2021 15:45:04
User entered empty.	Jessie Downs (b) (4)	23 Apr 2021 15:45:04
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 15:45:04

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'twice daily (BID)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 15:45:04

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:34:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 15:45:04

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 15:45:04

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 15:45:04

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:34:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered '14 Feb 2021'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 15:45:04

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:34:09

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered '0'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 15:45:04

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 15:45:04

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 15:45:04

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 15:45:04

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	23 Apr 2021 15:45:04

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 15:45:04

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Apr 2021 15:45:04

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:34:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:26:39
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 15:53:47
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 15:53:47
	(b) (4)	
Data point term sent to Coder	System	23 Apr 2021 15:53:01
User entered 'Eliquis'	Jessie Downs (b) (4)	23 Apr 2021 15:52:51
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:26:39
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	23 Apr 2021 15:52:51
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:26:39
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'atrial fibrillation'	Jessie Downs (b) (4)	23 Apr 2021 15:52:51
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:26:39
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '2.5'	Jessie Downs (b) (4)	23 Apr 2021 15:52:51
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:26:39
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'mg (mg)'	Jessie Downs (b) (4)	23 Apr 2021 15:52:51
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:26:39
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Apr 2021 15:52:51
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:26:39
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'twice daily (BID)'	Jessie Downs (b) (4)	23 Apr 2021 15:52:51
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:34:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:26:39
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Apr 2021 15:52:51
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:26:39
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'Oral (ORAL)'	Jessie Downs (b) (4)	23 Apr 2021 15:52:51
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:26:39
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Apr 2021 15:52:51
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:34:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:26:39
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '13 Feb 2021'	Jessie Downs (b) (4)	23 Apr 2021 15:52:51
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:26:39
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	23 Apr 2021 15:52:51
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:26:39
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	23 Apr 2021 15:52:51
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:26:39
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '16 Feb 2021'	Jessie Downs (b) (4)	23 Apr 2021 15:52:51
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:26:39
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	23 Apr 2021 15:52:51
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:26:39
User entered '2'	System	23 Apr 2021 15:52:51

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:26:39
User entered '1'	System	23 Apr 2021 15:52:51

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:26:39
User entered '804 (804)'	System	23 Apr 2021 15:52:51

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:34:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:16
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 22:16:08
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:25
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: GLUCOSE;HEPARIN SODIUM, PRODUCTSYNONYM: HEPARIN SODIUM IN DEXTROSE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 15:58:49
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 15:58:49
	(b) (4)	
Data point term sent to Coder	System	23 Apr 2021 15:55:05
User entered 'heparin sodiumin d 5 w'	Jessie Downs (b) (4)	23 Apr 2021 15:54:55
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:16
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 22:16:08
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:25
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	23 Apr 2021 15:54:55
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:16
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 22:16:08
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:25
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'atrial fibrillation'	Jessie Downs (b) (4)	23 Apr 2021 15:54:55
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:16
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 22:16:08
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:25
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '100'	Jessie Downs (b) (4)	23 Apr 2021 15:54:55
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:16
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 22:16:08
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:25
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'mL (mL)'	Jessie Downs (b) (4)	23 Apr 2021 15:54:55
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:16
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 22:16:08
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:25
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Apr 2021 15:54:55
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:16
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 22:16:08
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:25
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'as needed (PRN)'	Jessie Downs (b) (4)	23 Apr 2021 15:54:55
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:34:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:16
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 22:16:08
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:25
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Apr 2021 15:54:55
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:16
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 22:16:08
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:25
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Jessie Downs (b) (4)	23 Apr 2021 15:54:55
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:16
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 22:16:08
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:25
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Apr 2021 15:54:55
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:34:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:16
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 22:16:08
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:25
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '13 Feb 2021'	Jessie Downs (b) (4)	23 Apr 2021 15:54:55
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:34:09

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:16
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 22:16:08
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:25
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	23 Apr 2021 15:54:55
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:16
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 22:16:08
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:25
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	23 Apr 2021 15:54:55
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:16
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 22:16:08
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:25
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '13 Feb 2021'	Jessie Downs (b) (4)	23 Apr 2021 15:54:55
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:16
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 22:16:08
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:25
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	23 Apr 2021 15:54:55
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:16
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 22:16:08
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:25
User entered empty.	System	23 Apr 2021 15:54:55

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:16
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 22:16:08
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:25
User entered empty.	System	23 Apr 2021 15:54:55

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:16
Data hard unlocked.	(b) (4), (b) (6)	01 May 2021 22:16:08
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:25
User entered empty.	System	23 Apr 2021 15:54:55

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:34:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:27
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: GLUCOSE;HEPARIN SODIUM, PRODUCTSYNONYM: HEPARIN SODIUM IN DEXTROSE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 15:57:57
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 15:57:57
	(b) (4)	
Data point term sent to Coder	System	23 Apr 2021 15:56:06
User entered 'heparin sodium in d 5 w'	Jessie Downs (b) (4)	23 Apr 2021 15:55:58
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:27
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	23 Apr 2021 15:55:58
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:27
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'atrial fibrillation'	Jessie Downs (b) (4)	23 Apr 2021 15:55:58
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:27
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '25000'	Jessie Downs (b) (4)	23 Apr 2021 15:55:58
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:27
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'mL (mL)'	Jessie Downs (b) (4)	23 Apr 2021 15:55:58
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:27
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Apr 2021 15:55:58
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:27
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'as needed (PRN)'	Jessie Downs (b) (4)	23 Apr 2021 15:55:58
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:34:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:27
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Apr 2021 15:55:58
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:27
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Jessie Downs (b) (4)	23 Apr 2021 15:55:58
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:27
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Apr 2021 15:55:58
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:34:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:27
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '13 Feb 2021'	Jessie Downs (b) (4)	23 Apr 2021 15:55:58
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:27
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	23 Apr 2021 15:55:58
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:27
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	23 Apr 2021 15:55:58
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:27
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '13 Feb 2021'	Jessie Downs (b) (4)	23 Apr 2021 15:55:58
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:27
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	23 Apr 2021 15:55:58
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:27
User entered empty.	System	23 Apr 2021 15:55:58

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:27
User entered empty.	System	23 Apr 2021 15:55:58

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:27
User entered empty.	System	23 Apr 2021 15:55:58

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:34:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:30
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: PANCREATIC HORMONES, ATC: GLYCOGENOLYTIC HORMONES, ATC: GLYCOGENOLYTIC HORMONES, PRODUCT: GLUCAGON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 16:01:51
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 16:01:51
	(b) (4)	
Data point term sent to Coder	System	23 Apr 2021 15:58:11
User entered 'glucagon'	Jessie Downs (b) (4)	23 Apr 2021 15:57:44
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:30
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	23 Apr 2021 15:57:44
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:30
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'diabetes type ii'	Jessie Downs (b) (4)	23 Apr 2021 15:57:44
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:30
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '1'	Jessie Downs (b) (4)	23 Apr 2021 15:57:44
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:30
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'mg (mg)'	Jessie Downs (b) (4)	23 Apr 2021 15:57:44
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:30
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Apr 2021 15:57:44
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:30
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'as needed (PRN)'	Jessie Downs (b) (4)	23 Apr 2021 15:57:44
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:34:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:30
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Apr 2021 15:57:44
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:30
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Jessie Downs (b) (4)	23 Apr 2021 15:57:44
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:30
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Apr 2021 15:57:44
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:34:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:30
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '13 Feb 2021'	Jessie Downs (b) (4)	23 Apr 2021 15:57:44
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:30
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	23 Apr 2021 15:57:44
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:30
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	23 Apr 2021 15:57:44
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:30
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '16 Feb 2021'	Jessie Downs (b) (4)	23 Apr 2021 15:57:44
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:30
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	23 Apr 2021 15:57:44
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:30
User entered empty.	System	23 Apr 2021 15:57:44

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:30
User entered empty.	System	23 Apr 2021 15:57:44

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:15:30
User entered empty.	System	23 Apr 2021 15:57:44

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:34:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:47
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
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, PRODUCTSYNONYM: INSULIN, REGULAR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Apr 2021 13:10:15
	(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 Apr 2021 13:10:15
	(b) (4)	
Data point term sent to Coder	System	23 Apr 2021 16:00:12
User entered 'insulin regular human'	Jessie Downs (b) (4)	23 Apr 2021 15:59:19
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:47
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	23 Apr 2021 15:59:19
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:47
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'diabetes type ii'	Jessie Downs (b) (4)	23 Apr 2021 15:59:19
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:47
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	26 Apr 2021 17:26:27
Query 'Data is required. Please complete.' answered with 'sliding scale ' (Site from System).	Jessie Downs (b) (4)	23 Apr 2021 15:59:39
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Apr 2021 15:59:19
User entered empty.	Jessie Downs (b) (4)	23 Apr 2021 15:59:19
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:47
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	26 Apr 2021 17:26:29
Query 'Data is required. Please complete.' answered with 'sliding scale ' (Site from System).	Jessie Downs (b) (4)	23 Apr 2021 15:59:42
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Apr 2021 15:59:19
User entered empty.	Jessie Downs (b) (4)	23 Apr 2021 15:59:19
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:47
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Apr 2021 15:59:19
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:47
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'other (OTHER)'	Jessie Downs (b) (4)	23 Apr 2021 15:59:19
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:34:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:47
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'before meals and bedtime'	Jessie Downs (b) (4)	23 Apr 2021 15:59:19
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:47
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'Subcutaneous (SUBCUTANEOUS)'	Jessie Downs (b) (4)	23 Apr 2021 15:59:19
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:47
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Apr 2021 15:59:19
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:34:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:47
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '13 Feb 2021'	Jessie Downs (b) (4)	23 Apr 2021 15:59:19
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:47
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	23 Apr 2021 15:59:19
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:47
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	23 Apr 2021 15:59:19
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:47
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '16 Feb 2021'	Jessie Downs (b) (4)	23 Apr 2021 15:59:19
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:47
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	23 Apr 2021 15:59:19
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:47
User entered empty.	System	23 Apr 2021 15:59:19

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:47
User entered empty.	System	23 Apr 2021 15:59:19

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:47
User entered empty.	System	23 Apr 2021 15:59:19

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:34:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:49
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User coded data point as ATC: VARIOUS, ATC: ALL OTHER NON-THERAPEUTIC PRODUCTS, ATC: ALL OTHER NON-THERAPEUTIC PRODUCTS, ATC: SOLVENTS AND DILUTING AGENTS, INCL. IRRIGATING SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 16:04:51
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 16:04:51
	(b) (4)	
Data point term sent to Coder	System	23 Apr 2021 16:02:15
User entered 'sodium chloride 0.9'	Jessie Downs (b) (4)	23 Apr 2021 16:01:16
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:49
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	23 Apr 2021 16:01:16
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:49
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'flush iv catheter'	Jessie Downs (b) (4)	23 Apr 2021 16:01:16
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:49
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '10'	Jessie Downs (b) (4)	23 Apr 2021 16:01:16
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:49
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'mL (mL)'	Jessie Downs (b) (4)	23 Apr 2021 16:01:16
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:49
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Apr 2021 16:01:16
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:49
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'other (OTHER)'	Jessie Downs (b) (4)	23 Apr 2021 16:01:16
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:34:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:49
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'every 8 hours'	Jessie Downs (b) (4)	23 Apr 2021 16:01:16
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:49
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Jessie Downs (b) (4)	23 Apr 2021 16:01:16
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:49
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Apr 2021 16:01:16
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:34:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:49
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '13 Feb 2021'	Jessie Downs (b) (4)	23 Apr 2021 16:01:16
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:49
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	23 Apr 2021 16:01:16
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:49
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	23 Apr 2021 16:01:16
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:49
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '16 Feb 2021'	Jessie Downs (b) (4)	23 Apr 2021 16:01:16
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:49
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	23 Apr 2021 16:01:16
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:49
User entered empty.	System	23 Apr 2021 16:01:16

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:49
User entered empty.	System	23 Apr 2021 16:01:16

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:14:49
User entered empty.	System	23 Apr 2021 16:01:16

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:34:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:53
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 16:04:01
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 16:04:01
	(b) (4)	
Data point term sent to Coder	System	23 Apr 2021 16:03:16
User entered 'aspirin'	Jessie Downs (b) (4)	23 Apr 2021 16:02:53
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:53
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	23 Apr 2021 16:02:53
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:53
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'cardiac prophylaxis'	Jessie Downs (b) (4)	23 Apr 2021 16:02:53
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:53
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '325'	Jessie Downs (b) (4)	23 Apr 2021 16:02:53
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:53
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'mg (mg)'	Jessie Downs (b) (4)	23 Apr 2021 16:02:53
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:53
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Apr 2021 16:02:53
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:53
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'once (ONCE)'	Jessie Downs (b) (4)	23 Apr 2021 16:02:53
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:34:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:53
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Apr 2021 16:02:53
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:53
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'Oral (ORAL)'	Jessie Downs (b) (4)	23 Apr 2021 16:02:53
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:53
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Apr 2021 16:02:53
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:34:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:53
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '13 Feb 2021'	Jessie Downs (b) (4)	23 Apr 2021 16:02:53
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:53
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	23 Apr 2021 16:02:53
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:53
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	23 Apr 2021 16:02:53
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:53
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '13 Feb 2021'	Jessie Downs (b) (4)	23 Apr 2021 16:02:53
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:53
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	23 Apr 2021 16:02:53
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:53
User entered empty.	System	23 Apr 2021 16:02:53

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:53
User entered empty.	System	23 Apr 2021 16:02:53

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:16:53
User entered empty.	System	23 Apr 2021 16:02:53

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:34:09

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 16:05:51
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 16:05:51
	(b) (4)	
Data point term sent to Coder	System	23 Apr 2021 16:05:20
User entered 'aspirin'	Jessie Downs (b) (4)	23 Apr 2021 16:04:20
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:04:20

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'cardiac prophylaxis'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:04:20

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered '81'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:04:20

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:04:20

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:04:20

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'once daily (QD)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:04:20

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:34:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:04:20

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:04:20

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:04:20

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:34:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered '14 Feb 2021'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:04:20

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered '0'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:04:20

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Apr 2021 16:16:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Apr 2021 16:16:17
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4)	23 Apr 2021 16:16:17
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Apr 2021 16:04:20
User entered empty.	Jessie Downs (b) (4)	23 Apr 2021 16:04:20
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:04:20

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:04:20

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 16:04:20

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 16:04:20

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Apr 2021 16:04:20

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:34:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:17:40
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL BISULFATE, PRODUCTSYNONYM: PLAVIX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 16:06:59
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 16:06:59
	(b) (4)	
Data point term sent to Coder	System	23 Apr 2021 16:06:20
User entered 'Plavix'	Jessie Downs (b) (4)	23 Apr 2021 16:05:26
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:17:40
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	23 Apr 2021 16:05:26
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:17:40
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'acute coronary syndrome'	Jessie Downs (b) (4)	23 Apr 2021 16:05:26
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:17:40
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '75'	Jessie Downs (b) (4)	23 Apr 2021 16:05:26
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:17:40
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'mg (mg)'	Jessie Downs (b) (4)	23 Apr 2021 16:05:26
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:17:40
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Apr 2021 16:05:26
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:17:40
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'once daily (QD)'	Jessie Downs (b) (4)	23 Apr 2021 16:05:26
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:34:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:17:40
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Apr 2021 16:05:26
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:17:40
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'Oral (ORAL)'	Jessie Downs (b) (4)	23 Apr 2021 16:05:26
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:17:40
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Apr 2021 16:05:26
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:34:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:17:40
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '13 Feb 2021'	Jessie Downs (b) (4)	23 Apr 2021 16:05:26
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:17:40
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	23 Apr 2021 16:05:26
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:17:40
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	23 Apr 2021 16:05:26
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:17:40
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '16 Feb 2021'	Jessie Downs (b) (4)	23 Apr 2021 16:05:26
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:17:40
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	23 Apr 2021 16:05:26
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:17:40
User entered '1'	System	23 Apr 2021 16:05:26

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:17:40
User entered '1'	System	23 Apr 2021 16:05:26

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:17:40
User entered '804 (804)'	System	23 Apr 2021 16:05:26

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:34:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:17:42
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: CARBOHYDRATES, PRODUCT: GLUCOSE, PRODUCTSYNONYM: DEXTROSE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 16:24:03
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 16:24:03
	(b) (4)	
Data point term sent to Coder	System	23 Apr 2021 16:07:21
User entered 'dextrose'	Jessie Downs (b) (4)	23 Apr 2021 16:06:25
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:17:42
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	23 Apr 2021 16:06:25
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:17:42
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'severe hypoglycemia prophylaxis'	Jessie Downs (b) (4)	23 Apr 2021 16:06:25
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:17:42
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '50'	Jessie Downs (b) (4)	23 Apr 2021 16:06:25
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:17:42
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'mL (mL)'	Jessie Downs (b) (4)	23 Apr 2021 16:06:25
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:17:42
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Apr 2021 16:06:25
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:17:42
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'as needed (PRN)'	Jessie Downs (b) (4)	23 Apr 2021 16:06:25
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:34:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:17:42
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Apr 2021 16:06:25
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:17:42
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'Subcutaneous (SUBCUTANEOUS)'	Jessie Downs (b) (4)	23 Apr 2021 16:06:25
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:17:42
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Apr 2021 16:06:25
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:34:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:17:42
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '13 Feb 2021'	Jessie Downs (b) (4)	23 Apr 2021 16:06:25
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:17:42
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	23 Apr 2021 16:06:25
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:17:42
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	23 Apr 2021 16:06:25
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:17:42
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '16 Feb 2021'	Jessie Downs (b) (4)	23 Apr 2021 16:06:25
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:17:42
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	23 Apr 2021 16:06:25
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:17:42
User entered empty.	System	23 Apr 2021 16:06:25

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:17:42
User entered empty.	System	23 Apr 2021 16:06:25

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:17:42
User entered empty.	System	23 Apr 2021 16:06:25

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:34:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 16:31:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 16:31:00
Data point term sent to Coder	System	23 Apr 2021 16:08:22
User entered 'potassium chloride'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:07:41

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:07:41

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'hypopotassemia prophylaxis'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:07:41

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered '20'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:07:41

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'Other (OTHER)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:07:41

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'meq'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:07:41

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'as needed (PRN)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:07:41

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:34:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:07:41

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'Intravenous (INTRAVENOUS)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:07:41

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:07:41

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:34:09

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered '13 Feb 2021'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:07:41

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered '0'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:07:41

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Apr 2021 16:16:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Apr 2021 16:16:49
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4)	23 Apr 2021 16:16:49
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Apr 2021 16:07:41
User entered empty.	Jessie Downs (b) (4)	23 Apr 2021 16:07:41
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:07:41

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:07:41

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:07:41

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:07:41

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:07:41

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:34:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:22
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
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 LISPRO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 16:26:50
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 16:26:50
	(b) (4)	
Data point term sent to Coder	System	23 Apr 2021 16:12:27
User entered 'insulin lispro human'	Jessie Downs (b) (4)	23 Apr 2021 16:11:36
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:22
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	23 Apr 2021 16:11:36
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:22
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'diabetes type ii'	Jessie Downs (b) (4)	23 Apr 2021 16:11:36
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:22
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '9'	Jessie Downs (b) (4)	23 Apr 2021 16:11:36
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:22
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'Other (OTHER)'	Jessie Downs (b) (4)	23 Apr 2021 16:11:36
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:22
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'units'	Jessie Downs (b) (4)	23 Apr 2021 16:11:36
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:22
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'three times daily (TID)'	Jessie Downs (b) (4)	23 Apr 2021 16:11:36
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:34:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:22
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Apr 2021 16:11:36
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:22
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'Subcutaneous (SUBCUTANEOUS)'	Jessie Downs (b) (4)	23 Apr 2021 16:11:36
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:22
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Apr 2021 16:11:36
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:34:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:22
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '13 Feb 2021'	Jessie Downs (b) (4)	23 Apr 2021 16:11:36
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:22
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	23 Apr 2021 16:11:36
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:22
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	23 Apr 2021 16:11:36
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:22
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '16 Feb 2021'	Jessie Downs (b) (4)	23 Apr 2021 16:11:36
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:22
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	23 Apr 2021 16:11:36
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:22
User entered '3'	System	23 Apr 2021 16:11:36

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:22
User entered '1'	System	23 Apr 2021 16:11:36

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:22
User entered '804 (804)'	System	23 Apr 2021 16:11:36

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:34:09

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:24
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: GLYCERYL TRINITRATE, PRODUCTSYNONYM: NITROGLYCERIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 16:32:01
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 16:32:01
	(b) (4)	
Data point term sent to Coder	System	23 Apr 2021 16:13:27
User entered 'nitroglycerin'	Jessie Downs (b) (4)	23 Apr 2021 16:12:56
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:24
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	23 Apr 2021 16:12:56
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:24
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'chest pain'	Jessie Downs (b) (4)	23 Apr 2021 16:12:56
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:24
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '0.4'	Jessie Downs (b) (4)	23 Apr 2021 16:12:56
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:24
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'mg (mg)'	Jessie Downs (b) (4)	23 Apr 2021 16:12:56
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:24
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Apr 2021 16:12:56
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:24
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'twice daily (BID)'	Jessie Downs (b) (4)	23 Apr 2021 16:12:56
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:34:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:24
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	23 Apr 2021 16:12:56
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:24
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'Other (OTHER)'	Jessie Downs (b) (4)	23 Apr 2021 16:12:56
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:24
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'transdermal patch'	Jessie Downs (b) (4)	23 Apr 2021 16:12:56
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:34:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:24
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '13 Feb 2021'	Jessie Downs (b) (4)	23 Apr 2021 16:12:56
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:24
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	23 Apr 2021 16:12:56
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:24
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	23 Apr 2021 16:12:56
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:24
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '16 Feb 2021'	Jessie Downs (b) (4)	23 Apr 2021 16:12:56
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:24
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	23 Apr 2021 16:12:56
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:24
User entered '2'	System	23 Apr 2021 16:12:56

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:24
User entered '1'	System	23 Apr 2021 16:12:56

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:18:24
User entered '804 (804)'	System	23 Apr 2021 16:12:56

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:34:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 16:35:52
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 16:35:52
	(b) (4)	
Data point term sent to Coder	System	23 Apr 2021 16:15:29
User entered 'tramadol'	Jessie Downs (b) (4)	23 Apr 2021 16:14:32
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:14:32

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'left sciatic pain'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:14:32

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered '50'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:14:32

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:14:32

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:14:32

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'other (OTHER)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:14:32

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:34:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'every 6 hours'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:14:32

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:14:32

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:14:32

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:34:09

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered '13 Feb 2021'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:14:32

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:34:09

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered '0'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:14:32

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Apr 2021 16:17:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Apr 2021 16:17:16
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4)	23 Apr 2021 16:17:16
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Apr 2021 16:14:32
User entered empty.	Jessie Downs (b) (4)	23 Apr 2021 16:14:32
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:14:32

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:14:32

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:14:32

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:14:32

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:14:32

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:34:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 16:24:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 16:24:03
Data point term sent to Coder	System	23 Apr 2021 16:21:37
User entered 'enoxaparin sodium'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:20:38

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:20:38

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'heart attack prophylaxis'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:20:38

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered '0.4'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:20:38

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'mL (mL)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:20:38

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:20:38

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'once daily (QD)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:20:38

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:34:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:20:38

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'Subcutaneous (SUBCUTANEOUS)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:20:38

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:20:38

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:34:09

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered '13 Feb 2021'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:20:38

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:34:09

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered '0'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:20:38

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:20:38

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:20:38

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:20:38

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 16:20:38

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 16:20:38

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Apr 2021 16:20:38

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:34:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 16:36:55
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 16:36:55
	(b) (4)	
Data point term sent to Coder	System	23 Apr 2021 16:22:38
User entered 'morphine'	Jessie Downs (b) (4)	23 Apr 2021 16:21:49
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:21:49

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'left sciatic pain'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:21:49

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered '2'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:21:49

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:21:49

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:21:49

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'other (OTHER)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:21:49

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:34:09

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'every 4 hours / prn'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:21:49

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'Intravenous (INTRAVENOUS)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:21:49

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:21:49

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:34:09

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered '13 Feb 2021'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:21:49

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered '0'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:21:49

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:21:49

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:21:49

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:21:49

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:21:49

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:21:49

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:21:49

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:34:09

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
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 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 16:25:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 16:25:09
Data point term sent to Coder	System	23 Apr 2021 16:23:40
User entered 'insulin glargine'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:22:59

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:22:59

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'diabetes type ii'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:22:59

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered '28'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:22:59

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'Other (OTHER)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:22:59

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'units'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:22:59

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'other (OTHER)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:22:59

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:34:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'at bedtime'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:22:59

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'Subcutaneous (SUBCUTANEOUS)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:22:59

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:22:59

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:34:09

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered '13 Feb 2021'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:22:59

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered '0'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:22:59

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:22:59

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:22:59

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:22:59

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:22:59

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:22:59

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:22:59

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:34:09

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: POTASSIUM-SPARING AGENTS, ATC: ALDOSTERONE ANTAGONISTS, PRODUCT: SPIRONOLACTONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 16:35:06
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 16:35:06
	(b) (4)	
Data point term sent to Coder	System	23 Apr 2021 16:24:41
User entered 'spironolactone'	Jessie Downs (b) (4)	23 Apr 2021 16:23:54
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:23:54

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'chronic heart failure exacerbation'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:23:54

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered '25'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:23:54

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:23:54

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:23:54

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'once daily (QD)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:23:54

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:34:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:23:54

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:23:54

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:23:54

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:34:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered '13 Feb 2021'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:23:54

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered '0'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:23:54

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:23:54

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:23:54

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:23:54

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 16:23:54

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 16:23:54

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (60)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Apr 2021 16:23:54

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:34:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
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)	23 Apr 2021 16:28:17
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 16:28:17
	(b) (4)	
Data point term sent to Coder	System	23 Apr 2021 16:25:44
User entered 'atorvastatinal'	Jessie Downs (b) (4)	23 Apr 2021 16:25:10
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:25:10

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'hyperlipidemia'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:25:10

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered '80'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:25:10

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:25:10

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:25:10

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'other (OTHER)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:25:10

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:34:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'at bedtime'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:25:10

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:25:10

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:25:10

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:34:09

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'un UNK 2016'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:25:10

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered '0'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:25:10

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:25:10

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:25:10

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:25:10

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:25:10

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:25:10

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (61)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:25:10

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:34:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: BACLOFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 16:28:17
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 16:28:17
	(b) (4)	
Data point term sent to Coder	System	23 Apr 2021 16:26:57
User entered 'baclofen'	Jessie Downs (b) (4)	23 Apr 2021 16:25:54
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:25:54

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'left sciatic pain'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:25:54

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered '20'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:25:54

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:25:54

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:25:54

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'once daily (QD)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:25:54

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:34:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:25:54

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:25:54

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:25:54

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:34:09

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'un UNK 2018'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:25:54

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:34:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered '0'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:25:54

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:25:54

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:25:54

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:25:54

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 16:25:54

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 16:25:54

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (62)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Apr 2021 16:25:54

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:34:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: DICLOFENAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 16:33:04
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Apr 2021 16:33:04
	(b) (4)	
Data point term sent to Coder	System	23 Apr 2021 16:28:09
User entered 'diclofenac'	Jessie Downs (b) (4)	23 Apr 2021 16:27:00
	(b) (4)	

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:34:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:27:00

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'left sciatic pain'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:27:00

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:34:09

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered '50'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:27:00

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:34:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:27:00

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:34:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:27:00

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:34:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'as needed (PRN)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:27:00

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:34:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:27:00

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:34:09

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:27:00

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:34:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:27:00

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:34:09

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'un UNK 2018'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:27:00

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:34:09

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered '0'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:27:00

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:34:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:27:00

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:34:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered empty.	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:27:00

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:34:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:27:00

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:34:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:27:00

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:27:00

US3172250

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (63)

Generated On: 09 Jun 2021 15:34:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 16:27:00

US3172250

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:34:09

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:07:08
User closed query 'Per ETRTR: SAE "Shortness of Breath" required Concomitant medications, but no medications are present in this folder for SAE. Please add medication dosing details as appropriate, thanks.' (Site from CRA).	(b) (4), (b) (6)	26 Apr 2021 14:30:46
Query 'Per ETRTR: SAE "Shortness of Breath" required Concomitant medications, but no medications are present in this folder for SAE. Please add medication dosing details as appropriate, thanks.' answered with 'Concomitant medication log was updated.' (Site from CRA).	Jessie Downs (b) (4) (b) (4)	23 Apr 2021 16:28:32
User opened query 'Per ETRTR: SAE "Shortness of Breath" required Concomitant medications, but no medications are present in this folder for SAE. Please add medication dosing details as appropriate, thanks.' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 17:56:07
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:15:55
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	23 Nov 2020 16:20:35
User entered 'Yes (Y)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	23 Nov 2020 16:19:12
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	03 Sep 2020 16:09:00

US3172250

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:34:09

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '12 Sep 2020'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:26:03

US3172250

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:34:09

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'x-ray - ra ches'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:26:03

US3172250

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Adverse Event (AE)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:26:03

US3172250

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:34:09

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:26:03

US3172250

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:34:09

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:37:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '12 Sep 2020'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:26:43

US3172250

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:34:09

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:37:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'ct angio pulmonary arteries'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:26:43

US3172250

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:37:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Adverse Event (AE)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:26:43

US3172250

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:34:09

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:37:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:26:43

US3172250

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:34:09

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:37:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '12 Sep 2020'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:27:06

US3172250

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:34:09

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:37:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'ekg'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:27:06

US3172250

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:37:51
User closed query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. '(Site from DM).	(b) (4), (b) (6)	05 Mar 2021 14:51:55
Query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' answered with 'Concomitant procedure is written on the unscheduled progress note written by the Sub I.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	03 Mar 2021 15:20:28
User opened query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. '(Site from DM).	(b) (4), (b) (6)	02 Mar 2021 06:09:57
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Adverse Event (AE)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:27:06

US3172250

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:34:09

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:37:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:27:06

US3172250

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:34:09

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:37:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '13 Sep 2020'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:27:35

US3172250

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:34:09

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:37:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'x-ray - ra chest'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:27:35

US3172250

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:37:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Adverse Event (AE)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:27:35

US3172250

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:34:09

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:37:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:27:35

US3172250

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:34:09

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:37:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '13 Sep 2020'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:28:18

US3172250

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:34:09

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:37:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'ct lumbar spine'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:28:18

US3172250

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:37:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Adverse Event (AE)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:28:18

US3172250

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:34:09

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:37:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:28:18

US3172250

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:34:09

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:01
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered '15 Sep 2020'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:29:21

US3172250

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:34:09

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:01
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'us guidance paracentesis'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:29:21

US3172250

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:34:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:01
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered 'Adverse Event (AE)'	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:29:21

US3172250

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:34:09

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:38:01
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:29:21

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'USA-US118-2020-MRNA-1273-P301000010'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'Yes (Y)'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'No (N)'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'No (N)'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'Yes (Y)'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'No (N)'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'No (N)'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'No (N)'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'Mark'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'Kutner'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'FL'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 16:00:51
User entered 'US'	System	13 Nov 2020 17:58:14

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	03 May 2021 15:53:03
User entered '5'	System	26 Apr 2021 18:13:12
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Signature has been broken.	System	19 Feb 2021 15:39:19
User entered '4'	System	19 Feb 2021 15:39:19
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
User entered '3'	System	02 Dec 2020 13:25:50
User entered '2'	System	25 Nov 2020 16:01:00
User entered '1'	System	13 Nov 2020 17:58:14

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered		
'USA-US118-2020-MRNA-1273-P301000010'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'Yes (Y)'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'No (N)'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'No (N)'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'Yes (Y)'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'No (N)'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'No (N)'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'No (N)'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'Mark'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'Kutner'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'FL'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 16:00:51
User entered 'US'	System	13 Nov 2020 17:58:14

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	03 May 2021 15:53:03
User entered '5'	System	26 Apr 2021 18:13:12
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Signature has been broken.	System	19 Feb 2021 15:39:19
User entered '4'	System	19 Feb 2021 15:39:19
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
User entered '3'	System	02 Dec 2020 13:25:50
User entered '2'	System	25 Nov 2020 16:01:00
User entered '1'	System	13 Nov 2020 17:58:14

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:34:09

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
User entered '13/Nov/2020 12:58'	System	13 Nov 2020 17:58:14

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:34:09

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 16:00:51
User entered 'I'	(b) (4), (b) (6)	13 Nov 2020 17:58:14

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered		
'USA-US118-2020-MRNA-1273-P301000010'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'Yes (Y)'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'No (N)'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'No (N)'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'Yes (Y)'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'No (N)'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'No (N)'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'No (N)'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'Mark'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'Kutner'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'FL'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 16:00:51
User entered 'US'	System	13 Nov 2020 17:58:14

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	03 May 2021 15:53:03
User entered '5'	System	26 Apr 2021 18:13:12
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Signature has been broken.	System	19 Feb 2021 15:39:19
User entered '4'	System	19 Feb 2021 15:39:19
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
User entered '3'	System	02 Dec 2020 13:25:50
User entered '2'	System	25 Nov 2020 16:01:00
User entered '1'	System	13 Nov 2020 17:58:14

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:34:09

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
User entered '25/Nov/2020 11:00'	System	25 Nov 2020 16:01:00

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:34:09

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
Reviewed for Safety.	(b) (4), (b) (6)	02 Dec 2020 13:25:41
User entered 'I'	(b) (4), (b) (6)	25 Nov 2020 16:01:00

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered		
'USA-US118-2020-MRNA-1273-P301000010'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'Yes (Y)'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'No (N)'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'No (N)'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'Yes (Y)'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'No (N)'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'No (N)'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'No (N)'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'Mark'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'Kutner'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'FL'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 16:00:51
User entered 'US'	System	13 Nov 2020 17:58:14

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	03 May 2021 15:53:03
User entered '5'	System	26 Apr 2021 18:13:12
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Signature has been broken.	System	19 Feb 2021 15:39:19
User entered '4'	System	19 Feb 2021 15:39:19
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
User entered '3'	System	02 Dec 2020 13:25:50
User entered '2'	System	25 Nov 2020 16:01:00
User entered '1'	System	13 Nov 2020 17:58:14

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:34:09

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
User entered '02/Dec/2020 13:25'	System	02 Dec 2020 13:25:50

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:34:09

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 15:39:04
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	02 Dec 2020 13:25:50

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered		
'USA-US118-2020-MRNA-1273-P301000010'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'Yes (Y)'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'No (N)'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'No (N)'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'Yes (Y)'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'No (N)'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'No (N)'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'No (N)'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'Mark'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'Kutner'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'FL'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 16:00:51
User entered 'US'	System	13 Nov 2020 17:58:14

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	03 May 2021 15:53:03
User entered '5'	System	26 Apr 2021 18:13:12
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Signature has been broken.	System	19 Feb 2021 15:39:19
User entered '4'	System	19 Feb 2021 15:39:19
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
User entered '3'	System	02 Dec 2020 13:25:50
User entered '2'	System	25 Nov 2020 16:01:00
User entered '1'	System	13 Nov 2020 17:58:14

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:34:09

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
User entered '19/Feb/2021 09:39'	System	19 Feb 2021 15:39:19

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:34:09

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 18:12:34
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	19 Feb 2021 15:39:19

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered		
'USA-US118-2020-MRNA-1273-P301000010'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'Yes (Y)'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'No (N)'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'No (N)'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'Yes (Y)'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'No (N)'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'No (N)'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'No (N)'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'Mark'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'Kutner'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'FL'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 16:00:51
User entered 'US'	System	13 Nov 2020 17:58:14

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	03 May 2021 15:53:03
User entered '5'	System	26 Apr 2021 18:13:12
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Signature has been broken.	System	19 Feb 2021 15:39:19
User entered '4'	System	19 Feb 2021 15:39:19
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
User entered '3'	System	02 Dec 2020 13:25:50
User entered '2'	System	25 Nov 2020 16:01:00
User entered '1'	System	13 Nov 2020 17:58:14

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:34:09

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '26/Apr/2021 14:12'	System	26 Apr 2021 18:13:12

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:34:09

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'I'	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 18:13:12

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered		
'USA-US118-2020-MRNA-1273-P301000010'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'Yes (Y)'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'No (N)'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'No (N)'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'Yes (Y)'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'No (N)'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'No (N)'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'No (N)'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'Mark'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'Kutner'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 17:55:15
User entered 'FL'	System	13 Nov 2020 17:52:56

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:15:49
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 16:00:51
User entered 'US'	System	13 Nov 2020 17:58:14

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	03 May 2021 15:53:03
User entered '5'	System	26 Apr 2021 18:13:12
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Signature has been broken.	System	19 Feb 2021 15:39:19
User entered '4'	System	19 Feb 2021 15:39:19
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:15:49
	(b) (4)	
User entered '3'	System	02 Dec 2020 13:25:50
User entered '2'	System	25 Nov 2020 16:01:00
User entered '1'	System	13 Nov 2020 17:58:14

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:34:09

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '03/May/2021 11:52'	System	03 May 2021 15:53:03

US3172250

Folder: SAE USA-US118-2020-MRNA-1273-P301000010

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:34:09

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	03 May 2021 15:53:03

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'USA-US118-2021-MRNA-1273-P301000008'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'Yes (Y)'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'No (N)'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'No (N)'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'Yes (Y)'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'No (N)'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'No (N)'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:37:26
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'No (N)'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'Mark'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:37:26
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'Kutner'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:37:26
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'FL'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:02:52
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
User entered 'US'	System	19 Feb 2021 21:21:23

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	03 May 2021 16:07:09
User entered '4'	System	26 Apr 2021 17:20:17
User entered '3'	System	19 Apr 2021 15:08:14
User entered '2'	System	03 Mar 2021 16:02:48
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
User entered '1'	System	19 Feb 2021 21:21:23

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'USA-US118-2021-MRNA-1273-P301000008'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'Yes (Y)'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'No (N)'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'No (N)'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'Yes (Y)'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'No (N)'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'No (N)'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'No (N)'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'Mark'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'Kutner'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:37:26
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'FL'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:02:52
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
User entered 'US'	System	19 Feb 2021 21:21:23

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	03 May 2021 16:07:09
User entered '4'	System	26 Apr 2021 17:20:17
User entered '3'	System	19 Apr 2021 15:08:14
User entered '2'	System	03 Mar 2021 16:02:48
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
User entered '1'	System	19 Feb 2021 21:21:23

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:34:09

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
User entered '19/Feb/2021 21:21'	System	19 Feb 2021 21:21:23

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:34:09

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:02:52
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	19 Feb 2021 21:21:23

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'USA-US118-2021-MRNA-1273-P301000008'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'Yes (Y)'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'No (N)'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'No (N)'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'Yes (Y)'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'No (N)'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'No (N)'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'No (N)'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'Mark'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'Kutner'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:37:26
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'FL'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:02:52
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
User entered 'US'	System	19 Feb 2021 21:21:23

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	03 May 2021 16:07:09
User entered '4'	System	26 Apr 2021 17:20:17
User entered '3'	System	19 Apr 2021 15:08:14
User entered '2'	System	03 Mar 2021 16:02:48
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
User entered '1'	System	19 Feb 2021 21:21:23

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:34:09

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	09 Mar 2021 14:41:57
	(b) (4)	
User entered '03/Mar/2021 11:02'	System	03 Mar 2021 16:02:48

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:34:09

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:41:57
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:02:52
User entered 'I'	(b) (4), (b) (6)	03 Mar 2021 16:02:48

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'USA-US118-2021-MRNA-1273-P301000008'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'Yes (Y)'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'No (N)'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'No (N)'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'Yes (Y)'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'No (N)'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'No (N)'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'No (N)'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'Mark'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'Kutner'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:37:26
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'FL'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:02:52
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
User entered 'US'	System	19 Feb 2021 21:21:23

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	03 May 2021 16:07:09
User entered '4'	System	26 Apr 2021 17:20:17
User entered '3'	System	19 Apr 2021 15:08:14
User entered '2'	System	03 Mar 2021 16:02:48
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
User entered '1'	System	19 Feb 2021 21:21:23

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:34:09

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '19/Apr/2021 08:08'	System	19 Apr 2021 15:08:14

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:34:09

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 17:19:56
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	19 Apr 2021 15:08:14

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered		
'USA-US118-2021-MRNA-1273-P301000008'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'Yes (Y)'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'No (N)'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'No (N)'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:37:26
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'Yes (Y)'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'No (N)'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'No (N)'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:37:26
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'No (N)'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'Mark'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:37:26
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'Kutner'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:37:26
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'FL'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:02:52
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
User entered 'US'	System	19 Feb 2021 21:21:23

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	03 May 2021 16:07:09
User entered '4'	System	26 Apr 2021 17:20:17
User entered '3'	System	19 Apr 2021 15:08:14
User entered '2'	System	03 Mar 2021 16:02:48
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
User entered '1'	System	19 Feb 2021 21:21:23

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:34:09

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '26/Apr/2021 13:20'	System	26 Apr 2021 17:20:17

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:34:09

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'I'	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 17:20:17

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered		
'USA-US118-2021-MRNA-1273-P301000008'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'Yes (Y)'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'No (N)'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'No (N)'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'Yes (Y)'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'No (N)'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'No (N)'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'No (N)'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'Mark'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'Kutner'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:37:26
Reviewed for Safety.	(b) (4), (b) (6)	19 Feb 2021 21:21:16
User entered 'FL'	System	19 Feb 2021 21:20:56

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 16:02:52
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
User entered 'US'	System	19 Feb 2021 21:21:23

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	03 May 2021 16:07:09
User entered '4'	System	26 Apr 2021 17:20:17
User entered '3'	System	19 Apr 2021 15:08:14
User entered '2'	System	03 Mar 2021 16:02:48
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:37:26
	(b) (4)	
User entered '1'	System	19 Feb 2021 21:21:23

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:34:09

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '03/May/2021 12:07'	System	03 May 2021 16:07:09

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000008

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:34:09

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	03 May 2021 16:07:09

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'USA-US118-2021-MRNA-1273-P301000013'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'Yes (Y)'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'No (N)'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'No (N)'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'Yes (Y)'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'No (N)'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'No (N)'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'No (N)'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'Mark'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'Kutner'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'FL'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 10:25:14
User entered 'US'	System	25 Mar 2021 13:14:47

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	26 Apr 2021 15:14:09
User entered '4'	System	15 Apr 2021 10:25:31
User entered '3'	System	14 Apr 2021 17:56:06
User entered '2'	System	06 Apr 2021 18:12:08
User entered '1'	System	25 Mar 2021 13:14:47

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'USA-US118-2021-MRNA-1273-P301000013'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'Yes (Y)'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'No (N)'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'No (N)'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'Yes (Y)'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'No (N)'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'No (N)'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'No (N)'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'Mark'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'Kutner'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'FL'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 10:25:14
User entered 'US'	System	25 Mar 2021 13:14:47

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	26 Apr 2021 15:14:09
User entered '4'	System	15 Apr 2021 10:25:31
User entered '3'	System	14 Apr 2021 17:56:06
User entered '2'	System	06 Apr 2021 18:12:08
User entered '1'	System	25 Mar 2021 13:14:47

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:34:09

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '25/Mar/2021 09:14'	System	25 Mar 2021 13:14:47

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:34:09

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 10:25:14
User entered 'I'	(b) (4), (b) (6)	25 Mar 2021 13:14:47

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'USA-US118-2021-MRNA-1273-P301000013'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'Yes (Y)'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'No (N)'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'No (N)'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'Yes (Y)'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'No (N)'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'No (N)'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'No (N)'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'Mark'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'Kutner'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'FL'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 10:25:14
User entered 'US'	System	25 Mar 2021 13:14:47

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	26 Apr 2021 15:14:09
User entered '4'	System	15 Apr 2021 10:25:31
User entered '3'	System	14 Apr 2021 17:56:06
User entered '2'	System	06 Apr 2021 18:12:08
User entered '1'	System	25 Mar 2021 13:14:47

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:34:09

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '06/Apr/2021 14:11'	System	06 Apr 2021 18:12:08

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:34:09

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 10:25:14
User entered 'I'	(b) (4), (b) (6)	06 Apr 2021 18:12:08

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'USA-US118-2021-MRNA-1273-P301000013'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'Yes (Y)'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'No (N)'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'No (N)'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'Yes (Y)'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'No (N)'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'No (N)'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'No (N)'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'Mark'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'Kutner'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'FL'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 10:25:14
User entered 'US'	System	25 Mar 2021 13:14:47

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	26 Apr 2021 15:14:09
User entered '4'	System	15 Apr 2021 10:25:31
User entered '3'	System	14 Apr 2021 17:56:06
User entered '2'	System	06 Apr 2021 18:12:08
User entered '1'	System	25 Mar 2021 13:14:47

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:34:09

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '14/Apr/2021 13:55'	System	14 Apr 2021 17:56:06

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:34:09

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 10:25:14
User entered 'I'	(b) (4), (b) (6)	14 Apr 2021 17:56:06

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'USA-US118-2021-MRNA-1273-P301000013'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'Yes (Y)'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'No (N)'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'No (N)'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'Yes (Y)'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'No (N)'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'No (N)'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'No (N)'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'Mark'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'Kutner'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'FL'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 10:25:14
User entered 'US'	System	25 Mar 2021 13:14:47

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	26 Apr 2021 15:14:09
User entered '4'	System	15 Apr 2021 10:25:31
User entered '3'	System	14 Apr 2021 17:56:06
User entered '2'	System	06 Apr 2021 18:12:08
User entered '1'	System	25 Mar 2021 13:14:47

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:34:09

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered '15/Apr/2021 10:25'	System	15 Apr 2021 10:25:31

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:34:09

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 15:13:39
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	15 Apr 2021 10:25:31

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'USA-US118-2021-MRNA-1273-P301000013'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'Yes (Y)'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'No (N)'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'No (N)'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'Yes (Y)'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'No (N)'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'No (N)'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'No (N)'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'Mark'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'Kutner'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:26:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Mar 2021 13:14:34
User entered 'FL'	System	25 Mar 2021 13:14:16

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:26:40
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 10:25:14
User entered 'US'	System	25 Mar 2021 13:14:47

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:34:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	26 Apr 2021 15:14:09
User entered '4'	System	15 Apr 2021 10:25:31
User entered '3'	System	14 Apr 2021 17:56:06
User entered '2'	System	06 Apr 2021 18:12:08
User entered '1'	System	25 Mar 2021 13:14:47

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:34:09

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	28 Apr 2021 07:34:11
	(b) (4)	
User entered '26/Apr/2021 11:13'	System	26 Apr 2021 15:14:09

US3172250

Folder: SAE USA-US118-2021-MRNA-1273-P301000013

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:34:09

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:34:11
User entered 'I'	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 15:14:09