

US3372184 (Prod: Palm Beach Research Center)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:14:43

All time stamps listed in this document are displayed in GMT

US3372184

Form: Participant Creation

Data signed: (b) (4) 16 Feb 2021 19:42:17

Generated On: 09 Jun 2021 17:14:43

[Participant ID](#)

US3372184

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

US3372184

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 03:11:53

Generated On: 09 Jun 2021 17:14:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 16 Feb 2021 23:05:28

Generated On: 09 Jun 2021 17:14:43

Date of Birth (MMM yyyy)	(b) (6) 1947
Age	72
Age Units	YEARS
Age (Derived)	72
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 16 Feb 2021 23:24:17

Generated On: 09 Jun 2021 17:14:43

Date of Informed Consent (<i>dd MMM yyyy</i>)	19 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3372184

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 17 Feb 2021 00:18:03

Generated On: 09 Jun 2021 17:14:43

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 17 Feb 2021 00:50:17

Generated On: 09 Jun 2021 17:14:43

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 17 Feb 2021 00:34:03

Generated On: 09 Jun 2021 17:14:43

Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN UNK 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2009
Start Year (derived)	2009
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 17 Feb 2021 00:34:03

Generated On: 09 Jun 2021 17:14:43

Condition	ESSENTIAL TREMORS
Start date (dd MMM yyyy)	UN UNK 1997
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 1997
Start Year (derived)	1997
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 17 Feb 2021 00:34:03

Generated On: 09 Jun 2021 17:14:43

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 17 Feb 2021 00:34:03

Generated On: 09 Jun 2021 17:14:43

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 17 Feb 2021 00:34:03

Generated On: 09 Jun 2021 17:14:43

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 1970
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 1970
Start Year (derived)	1970
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 17 Feb 2021 00:34:03

Generated On: 09 Jun 2021 17:14:43

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 17 Feb 2021 00:34:03

Generated On: 09 Jun 2021 17:14:43

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 1974
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 1974
Start Year (derived)	1974
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 17 Feb 2021 00:34:03

Generated On: 09 Jun 2021 17:14:43

Condition	SINUSITIS
Start date (dd MMM yyyy)	UN UNK 1994
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 1994
Start Year (derived)	1994
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 17 Feb 2021 00:34:03

Generated On: 09 Jun 2021 17:14:43

Condition	ALLERGY - ENVIRONMENTAL
Start date (dd MMM yyyy)	UN UNK 1994
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 1994
Start Year (derived)	1994
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 17 Feb 2021 00:34:03

Generated On: 09 Jun 2021 17:14:43

Condition	GENITAL HERPES
Start date (dd MMM yyyy)	UN UNK 1958
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 1958
Start Year (derived)	1958
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 17 Feb 2021 00:34:03

Generated On: 09 Jun 2021 17:14:43

Condition	ERECTILE DYSFUNCTION
Start date (dd MMM yyyy)	UN UNK 1999
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 1999
Start Year (derived)	1999
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 17 Feb 2021 00:34:03

Generated On: 09 Jun 2021 17:14:43

Condition	GENERALIZED OSTEOARTHRITIS
Start date (dd MMM yyyy)	UN UNK 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 17 Feb 2021 00:34:03

Generated On: 09 Jun 2021 17:14:43

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

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 17 Feb 2021 00:34:03

Generated On: 09 Jun 2021 17:14:43

Condition	OSTEOPENIA
Start date (dd MMM yyyy)	UN UNK 1999
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 1999
Start Year (derived)	1999
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 17 Feb 2021 00:34:03

Generated On: 09 Jun 2021 17:14:43

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

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 17 Feb 2021 00:34:03

Generated On: 09 Jun 2021 17:14:43

Condition	CATARACTS BILATERAL
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 17 Feb 2021 00:34:03

Generated On: 09 Jun 2021 17:14:43

Condition	CATARACTS SURGERY BILATERAL
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 17 Feb 2021 00:34:03

Generated On: 09 Jun 2021 17:14:43

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

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 17 Feb 2021 00:34:03

Generated On: 09 Jun 2021 17:14:43

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

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 17 Feb 2021 00:34:03

Generated On: 09 Jun 2021 17:14:43

Condition	VOCAL CORD POLYPS
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	JAN 2005
Stop Year (derived)	2005

US3372184

Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 17 Feb 2021 00:34:03

Generated On: 09 Jun 2021 17:14:43

Condition	VOCAL CORD POLYPECTOMY
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	JAN 2005
Stop Year (derived)	2005

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 03:28:17

Generated On: 09 Jun 2021 17:14:43

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	19 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	15:00 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 15:00
Height (<i>xxx.x</i>)	162.6 cm
Weight (<i>xxx.x</i>)	59.6 kg
BMI (<i>xxx.x</i>)	22.54266 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 01:05:56

Generated On: 09 Jun 2021 17:14:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 17 Feb 2021 02:16:14

Generated On: 09 Jun 2021 17:14:43

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 17 Feb 2021 02:16:14

Generated On: 09 Jun 2021 17:14:43

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 03:11:53

Generated On: 09 Jun 2021 17:14:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 17 Feb 2021 01:59:31

Generated On: 09 Jun 2021 17:14:43

What was the date of randomization? (dd MMM yyyy) 19 AUG 2020

What was the participant's randomization number? 187082

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 17 Feb 2021 03:44:35

Generated On: 09 Jun 2021 17:14:43

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 03:44:35

Generated On: 09 Jun 2021 17:14:43

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)	19 AUG 2020
Time of assessment (00:00-23:59)	15:00 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 15:00
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	52 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	152 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 03:44:35

Generated On: 09 Jun 2021 17:14:43

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)	19 AUG 2020
Time of assessment (00:00-23:59)	16:40 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 16:40
Temperature (xxx.x)	36.1 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	48 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 01:05:56

Generated On: 09 Jun 2021 17:14:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 23:39:55

Generated On: 09 Jun 2021 17:14:43

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) 19 AUG 2020

What was the treatment time? (00:00-23:59) 16:09 (24 HR)

Treatment Date and Time (derived) 19 AUG 2020 16:09

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 00:01:40

Generated On: 09 Jun 2021 17:14:43

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 AUG 2020
Collection time (00:00-23:59)	15:35 (24 HR)
Collection date and time (derived)	19 AUG 2020 15:35

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 17:17:19

Generated On: 09 Jun 2021 17:14:43

Collection date (dd MMM yyyy)			19 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:32	19 AUG 2020 15:32
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:33:34

Generated On: 09 Jun 2021 17:14:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °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

19 AUG 2020 16:49

PC Open Date & Time

19 AUG 2020 16:29

PC Close Date & Time

19 AUG 2020 18:59

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.5 °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	20 AUG 2020 05:50
PC Open Date & Time	19 AUG 2020 19:54
PC Close Date & Time	20 AUG 2020 11:59

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:14:43

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

97.5 °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

20 AUG 2020 17:06

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:14:43

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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 12:26

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:14:43

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

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 12:53

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:14:43

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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 12:08

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 13:26

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:14:43

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

98.0 °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 12:10

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

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

19 AUG 2020 16:50

PC Open Date & Time

19 AUG 2020 16:29

PC Close Date & Time

19 AUG 2020 18:59

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

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 05:51

PC Open Date & Time

19 AUG 2020 19:54

PC Close Date & Time

20 AUG 2020 11:59

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:14:43

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

20 AUG 2020 17:06

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:14:43

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

21 AUG 2020 12:27

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:14:43

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

22 AUG 2020 12:53

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:14:43

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

23 AUG 2020 12:09

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:14:43

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

24 AUG 2020 13:26

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:14:43

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

25 AUG 2020 12:10

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

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 ☐

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

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

No ☒

Yes ☐

PC Time stamp	19 AUG 2020 16:50
PC Open Date & Time	19 AUG 2020 16:29
PC Close Date & Time	19 AUG 2020 18:59

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

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 ☐

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 05:52
PC Open Date & Time	19 AUG 2020 19:54
PC Close Date & Time	20 AUG 2020 11:59

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:14:43

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 17:07
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:14:43

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 12:28
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:14:43

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)

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US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:14:43

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 12:54
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:14:43

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 12:09
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:14:43

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 13:27
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:14:43

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

US3372184

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:32:59

Generated On: 09 Jun 2021 17:14:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372184

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:33:34

Generated On: 09 Jun 2021 17:14:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372184

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:32:47

Generated On: 09 Jun 2021 17:14:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372184

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:33:34

Generated On: 09 Jun 2021 17:14:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372184

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:32:47

Generated On: 09 Jun 2021 17:14:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372184

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:33:34

Generated On: 09 Jun 2021 17:14:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372184

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 20:18:41

Generated On: 09 Jun 2021 17:14:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3372184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 20:18:41

Generated On: 09 Jun 2021 17:14:43

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)	22 SEP 2020
Time of assessment (00:00-23:59)	14:35 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 14:35
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)	54 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	160 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3372184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 20:18:41

Generated On: 09 Jun 2021 17:14:43

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)	22 SEP 2020
Time of assessment (00:00-23:59)	16:21 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 16:21
Temperature (xxx.x)	35.8 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	45 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	164 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3372184

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 20:18:41

Generated On: 09 Jun 2021 17:14:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 SEP 2020

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

US3372184

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 20:18:41

Generated On: 09 Jun 2021 17:14:43

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) 22 SEP 2020

What was the treatment time? (00:00-23:59) 15:42 (24 HR)

Treatment Date and Time (derived) 22 SEP 2020 15:42

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

US3372184

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 20:18:41

Generated On: 09 Jun 2021 17:14:43

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 SEP 2020
Collection time (00:00-23:59)	15:03 (24 HR)
Collection date and time (derived)	22 SEP 2020 15:03

US3372184

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 17:17:19

Generated On: 09 Jun 2021 17:14:43

Collection date (dd MMM yyyy)			22 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:59	22 SEP 2020 14:59
Nasopharyngeal Swab 2	No		

US3372184

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:33:34

Generated On: 09 Jun 2021 17:14:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

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

96.5 °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

22 SEP 2020 16:22

PC Open Date & Time

22 SEP 2020 16:02

PC Close Date & Time

22 SEP 2020 18:32

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

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):

PC Time Stamp	23 SEP 2020 05:27
PC Open Date & Time	22 SEP 2020 19:27
PC Close Date & Time	23 SEP 2020 11:59

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:14:43

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

24 SEP 2020 05:25

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 08:24

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:14:43

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

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 05:59

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:14:43

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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 06:39

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 SEP 2020 07:53

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:14:43

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

97.7 °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

29 SEP 2020 11:21

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

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

22 SEP 2020 16:22

PC Open Date & Time

22 SEP 2020 16:02

PC Close Date & Time

22 SEP 2020 18:32

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

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

23 SEP 2020 05:28

PC Open Date & Time

22 SEP 2020 19:27

PC Close Date & Time

23 SEP 2020 11:59

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:14:43

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

24 SEP 2020 05:26

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:14:43

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

25 SEP 2020 08:24

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:14:43

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

26 SEP 2020 06:00

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:14:43

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

27 SEP 2020 06:39

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:14:43

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

28 SEP 2020 07:56

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:14:43

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

29 SEP 2020 11:22

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

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 ☐

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

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

No ☒

Yes ☐

PC Time stamp	22 SEP 2020 16:23
PC Open Date & Time	22 SEP 2020 16:02
PC Close Date & Time	22 SEP 2020 18:32

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

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 ☐

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

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

No ☒

Yes ☐

PC Time stamp	23 SEP 2020 05:29
PC Open Date & Time	22 SEP 2020 19:27
PC Close Date & Time	23 SEP 2020 11:59

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:14:43

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 ☒

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:14:43

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 05:26
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:14:43

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

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:14:43

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

112 of 2877

EAB) (1725)

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:14:43

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

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:14:43

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 ☒

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:14:43

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 06:39
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:14:43

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 07:57
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:14:43

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 11:22
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3372184

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:32:47

Generated On: 09 Jun 2021 17:14:43

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

US3372184

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:33:34

Generated On: 09 Jun 2021 17:14:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372184

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:32:47

Generated On: 09 Jun 2021 17:14:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372184

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:33:34

Generated On: 09 Jun 2021 17:14:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372184

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:32:59

Generated On: 09 Jun 2021 17:14:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372184

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:33:34

Generated On: 09 Jun 2021 17:14:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372184

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 19:59:32

Generated On: 09 Jun 2021 17:14:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3372184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 19:59:32

Generated On: 09 Jun 2021 17:14:43

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

Time of assessment (00:00-23:59) _____

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3372184

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 19:59:32

Generated On: 09 Jun 2021 17:14:43

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.

US3372184

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 19:59:32

Generated On: 09 Jun 2021 17:14:43

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 OCT 2020
Collection time (00:00-23:59)	14:14 (24 HR)
Collection date and time (derived)	14 OCT 2020 14:14

US3372184

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:33:34

Generated On: 09 Jun 2021 17:14:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 OCT 2020 08:43:55

Patient Cloud Open Date & Time

19 OCT 2020 00:01

Patient Cloud Close Date & Time

23 OCT 2020 23:59

US3372184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 OCT 2020 06:04:26

Patient Cloud Open Date & Time

26 OCT 2020 00:01

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3372184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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	02 NOV 2020 09:04:05
Patient Cloud Open Date & Time	02 NOV 2020 00:01
Patient Cloud Close Date & Time	06 NOV 2020 23:59

US3372184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

18 NOV 2020 13:02:12

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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	23 NOV 2020 03:38:32
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

27 NOV 2020 03:41:55

Patient Cloud Open Date & Time

27 NOV 2020 00:01

Patient Cloud Close Date & Time

01 DEC 2020 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

04 DEC 2020 00:01:55

Patient Cloud Open Date & Time

04 DEC 2020 00:01

Patient Cloud Close Date & Time

08 DEC 2020 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

11 DEC 2020 05:30:42

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 DEC 2020 18:58:49

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

25 DEC 2020 02:32:32

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

01 JAN 2021 02:06:29

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 JAN 2021 12:00:46

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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 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	15 JAN 2021 02:47:25
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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	22 JAN 2021 04:48:58
Patient Cloud Open Date & Time	22 JAN 2021 00:01
Patient Cloud Close Date & Time	26 JAN 2021 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 JAN 2021 04:44:13

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

05 FEB 2021 04:01:13

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 FEB 2021 04:19:57
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 FEB 2021 02:01:42

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

26 FEB 2021 08:44:18

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 MAR 2021 00:09:34

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 MAR 2021 00:03:06

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	19 MAR 2021 01:19:16
Patient Cloud Open Date & Time	19 MAR 2021 00:01
Patient Cloud Close Date & Time	23 MAR 2021 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

26 MAR 2021 01:06:44

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

02 APR 2021 02:31:27

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

09 APR 2021 00:05:27

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

16 APR 2021 03:30:26

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

23 APR 2021 03:42:48

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

30 APR 2021 05:47:23

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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 ☐

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

DAY 285

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

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

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

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

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

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

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

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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 ☐

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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 ☐

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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 ☐

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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"/>

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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 <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"/>

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

DAY 334

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 JUL 2021 00:01
Patient Cloud Close Date & Time	20 JUL 2021 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 2021 00:01
Patient Cloud Close Date & Time	27 JUL 2021 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

DAY 348

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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 ☐

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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 ☐

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 2021 00:01
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Patient Cloud Close Date & Time	17 AUG 2021 23:59
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US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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 ☐

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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 ☐

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 2021 00:01
Patient Cloud Close Date & Time	31 AUG 2021 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 2021 00:01
Patient Cloud Close Date & Time	07 SEP 2021 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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 ☐

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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°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 ☐

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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 ☐

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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 ☐ Yes ☐

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 2021 00:01
Patient Cloud Close Date & Time	05 OCT 2021 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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°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 ☐

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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 ☐

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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 ☐

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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 ☐

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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 ☐

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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"/>

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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 ☐

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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"/>

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 DEC 2021 00:01
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Patient Cloud Close Date & Time	28 DEC 2021 23:59
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US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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 ☐

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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 ☐

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JAN 2022 00:01
Patient Cloud Close Date & Time	25 JAN 2022 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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 ☐

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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 ☐

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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 ☐

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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 ☐

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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 ☐

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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°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 ☐

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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°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 ☐

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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"/>

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 APR 2022 00:01
Patient Cloud Close Date & Time	12 APR 2022 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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"/>

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

DAY 642

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

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

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

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

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

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

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

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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 ☐

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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 ☐

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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 ☐

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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="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"/>

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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 ☐

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUN 2022 00:01
Patient Cloud Close Date & Time	28 JUN 2022 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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 ☐
Yes ☐

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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 ☐

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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 ☐

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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 ☐ Yes ☐

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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"/>

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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 ☐

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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 ☐

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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°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 ☐

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	30 SEP 2022 00:01
Patient Cloud Close Date & Time	04 OCT 2022 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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 ☐

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 OCT 2022 00:01
Patient Cloud Close Date & Time	11 OCT 2022 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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 ☐

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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"/>

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

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

Date and time of submission	
Patient Cloud Open Date & Time	21 OCT 2022 00:01
Patient Cloud Close Date & Time	25 OCT 2022 23:59

US3372184

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:14:43

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		05 MAR 2021 00:09:05

US3372184

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:32:59

Generated On: 09 Jun 2021 17:14:43

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 17 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3372184

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:33:34

Generated On: 09 Jun 2021 17:14:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372184

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:32:47

Generated On: 09 Jun 2021 17:14:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372184

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:33:34

Generated On: 09 Jun 2021 17:14:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372184

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:32:47

Generated On: 09 Jun 2021 17:14:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372184

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:33:34

Generated On: 09 Jun 2021 17:14:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372184

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:32:47

Generated On: 09 Jun 2021 17:14:43

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3372184

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:33:34

Generated On: 09 Jun 2021 17:14:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372184

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Mar 2021 19:21:44

Generated On: 09 Jun 2021 17:14:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3372184

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 31 Mar 2021 14:26:03

Generated On: 09 Jun 2021 17:14:43

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	15 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	13:52 (24 HR)
Vital Signs Date and Time (derived)	15 MAR 2021 13:52
Temperature (<i>xxx.x</i>)	36.7 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (<i>xxx</i>)	60 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	66 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3372184

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Mar 2021 19:21:44

Generated On: 09 Jun 2021 17:14:43

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.

US3372184

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Mar 2021 19:21:44

Generated On: 09 Jun 2021 17:14:43

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 MAR 2021
Collection time (00:00-23:59)	14:23 (24 HR)
Collection date and time (derived)	15 MAR 2021 14:23

US3372184

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Mar 2021 19:21:44

Generated On: 09 Jun 2021 17:14:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372184

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 20 Apr 2021 18:29:13

Generated On: 09 Jun 2021 17:14:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372184

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 20 Apr 2021 18:29:13

Generated On: 09 Jun 2021 17:14:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372184

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:43

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

US3372184

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:43

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3372184

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:14:43

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

US3372184

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:14:43

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3372184

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

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 03:11:53

Generated On: 09 Jun 2021 17:14:43

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

Visit date (dd MMM yyyy)	14 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3372184

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

Form: Unblinding

Data signed: (b) (4) 14 Apr 2021 18:06:56

Generated On: 09 Jun 2021 17:14:43

Date of updated informed consent (<i>dd MMM yyyy</i>)	14 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>)	14 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3372184

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 17 Feb 2021 03:44:35

Generated On: 09 Jun 2021 17:14:43

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

US3372184

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 03:44:35

Generated On: 09 Jun 2021 17:14:43

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 JAN 2021
Time of assessment (00:00-23:59)	14:50 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 14:50
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	160 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3372184

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 03:44:35

Generated On: 09 Jun 2021 17:14:43

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 JAN 2021
Time of assessment (00:00-23:59)	16:30 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 16:30
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	158 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3372184

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

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 01:05:56

Generated On: 09 Jun 2021 17:14:43

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.

US3372184

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

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 23:39:55

Generated On: 09 Jun 2021 17:14:43

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) 14 JAN 2021

What was the treatment time? (00:00-23:59) 15:14 (24 HR)

Treatment Date and Time (derived) 14 JAN 2021 15:14

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

What was the frequency of the study treatment dosing? ONCE

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

US3372184

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 00:01:40

Generated On: 09 Jun 2021 17:14:43

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 JAN 2021

Collection time (00:00-23:59)

14:14 (24 HR)

Collection date and time (derived)

14 JAN 2021 14:14

US3372184

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 16 Feb 2021 17:34:24

Generated On: 09 Jun 2021 17:14:43

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 JAN 2021
Collection time (00:00 - 23:59)	14:11
Collection Date and Time (derived)	14 JAN 2021 14:11

US3372184

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

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:33:34

Generated On: 09 Jun 2021 17:14:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372184

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 02:32:59

Generated On: 09 Jun 2021 17:14:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372184

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:33:34

Generated On: 09 Jun 2021 17:14:43

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

US3372184

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 03:11:53

Generated On: 09 Jun 2021 17:14:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3372184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 03:44:35

Generated On: 09 Jun 2021 17:14:43

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 FEB 2021
Time of assessment (00:00-23:59)	12:15 (24 HR)
Vital Signs Date and Time (derived)	12 FEB 2021 12:15
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	159 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3372184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 03:44:35

Generated On: 09 Jun 2021 17:14:43

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 FEB 2021
Time of assessment (00:00-23:59)	13:18 (24 HR)
Vital Signs Date and Time (derived)	12 FEB 2021 13:18
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3372184

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 01:05:56

Generated On: 09 Jun 2021 17:14:43

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.

US3372184

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 23:39:55

Generated On: 09 Jun 2021 17:14:43

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 12 FEB 2021

What was the treatment time? (00:00-23:59) 12:45 (24 HR)

Treatment Date and Time (derived) 12 FEB 2021 12:45

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

US3372184

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:33:34

Generated On: 09 Jun 2021 17:14:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372184

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:28:55

Generated On: 09 Jun 2021 17:14:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3372184

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:28:55

Generated On: 09 Jun 2021 17:14:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372184

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Mar 2021 19:21:43

Generated On: 09 Jun 2021 17:14:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3372184

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Mar 2021 19:21:43

Generated On: 09 Jun 2021 17:14:43

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	15 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	13:52 (24 HR)
Vital Signs Date and Time (derived)	15 MAR 2021 13:52
Temperature (<i>xxx.x</i>)	36.7 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (<i>xxx</i>)	60 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	66 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3372184

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Mar 2021 19:21:43

Generated On: 09 Jun 2021 17:14:43

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.

US3372184

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Mar 2021 19:20:40

Generated On: 09 Jun 2021 17:14:43

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 MAR 2021
Collection time (00:00-23:59)	14:23 (24 HR)
Collection date and time (derived)	15 MAR 2021 14:23

US3372184

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 16 Feb 2021 16:45:28

Generated On: 09 Jun 2021 17:14:43

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3372184

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 05 Apr 2021 18:39:57

Generated On: 09 Jun 2021 17:14:43

AEID	USA-US056-2020-MRNA-1273-P30 1000002
Adverse event	APPENDICITIS
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)	02 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)	02 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)	02 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	06 SEP 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 05 Apr 2021 18:39:57

Generated On: 09 Jun 2021 17:14:43

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input 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	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	SUBJECT CONTACTED THE SITE AND WAS ADMITTED TO THE HOSPITAL 09/02/2020, WITH ACUTE APPENDICITIS, HAD APPENDECTOMY PERFORMED SAME DAY.
Serious Adverse Event Derived (CSA Programming Field Only)	1
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Folder: Adverse Events

Form: Adverse Events (1)

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

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 05 Apr 2021 18:39:57

Generated On: 09 Jun 2021 17:14:43

AEID

Adverse event

RIGHT LOWER ABDOMINAL
PAIN

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

28 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

28 AUG 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 05 Apr 2021 18:39:57

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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 05 Apr 2021 18:39:57

Generated On: 09 Jun 2021 17:14:43

AEID	
Adverse event	LOOSE STOOL
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)	29 AUG 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)	30 AUG 2020
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	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 05 Apr 2021 18:39:57

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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 05 Apr 2021 18:39:57

Generated On: 09 Jun 2021 17:14:43

AEID	
Adverse event	NAUSEA
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)	02 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)	05 SEP 2020
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	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 05 Apr 2021 18:39:57

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input 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 _____ _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 17 Feb 2021 01:43:53

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

Name of Medication ESOMEPRAZOLE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Apr 2021 18:39:58

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	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 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Apr 2021 18:39:58

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Name of Medication PROPRANOLOL

Prophylaxis Yes ☐
No ☒

Indication ESSENTIAL TREMORS

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

	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 1999
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Apr 2021 18:39:58

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Name of Medication TAMSULOSIN

Prophylaxis Yes ☐
No ☒

Indication BENIGN PROSTATIC
HYPERPLASIA (BPH)

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

	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 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 05 Apr 2021 18:39:58

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Name of Medication TAMSULOSIN

Prophylaxis Yes ☐
No ☒

Indication URINARY RETENTION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

Name of Medication LOSARTAN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 05 Apr 2021 18:39:58

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

	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 2005	
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)	2	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 05 Apr 2021 18:39:58

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Name of Medication ATENOLOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 1995	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

Name of Medication ALPRAZOLAM

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 0.25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

Name of Medication AZELASTINE

Prophylaxis Yes ☐
No ☒

Indication SINUSITIS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 1994
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

Name of Medication FAMCICLOVIR

Prophylaxis Yes ☐
No ☒

Indication GENITAL HERPES

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2009	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

Name of Medication SILDENAFIL

Prophylaxis Yes ☐
No ☒

Indication ERECTILE DYSFUNCTION

Dose per administration 35

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

	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 1999	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

Name of Medication CELECOXIB

Prophylaxis Yes ☐
No ☒

Indication GENERALIZED
OSTEOARTHRITIS PAIN

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

	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 2002	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

Name of Medication NAPROXEN

Prophylaxis Yes ☐
No ☒

Indication GENERALIZED
OSTEOARTHRITIS PAIN

Dose per administration 550

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

	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 1995	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

Name of Medication DOCUSATE

Prophylaxis Yes ☒
No ☐

Indication CONSTIPATION
PROPHYLAXIS/PREVENTION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

Name of Medication MIRALAX

Prophylaxis Yes ☒
No ☐

Indication CONSTIPATION
PROPHYLAXIS/PREVENTION

Dose per administration 8500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

Name of Medication MULTI-VITAMINS

Prophylaxis Yes ☐
No ☒

Indication DIETARY SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

	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 1975	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

Name of Medication VITAMIN D3

Prophylaxis Yes ☐
No ☒

Indication DIETARY SUPPLEMENT

Dose per administration 2000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

	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 2009	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

Name of Medication CALCIUM

Prophylaxis Yes ☐
No ☒

Indication DIETARY SUPPLEMENT

Dose per administration 2000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2009	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

Name of Medication DIPHTHERIA TETANUS AND
ACELLULAR PERTUSSIS
VACCINE

Prophylaxis Yes ☒
No ☐

Indication DIPHTHERIA TETANUS AND
ACELLULAR PERTUSSIS
PROPHYLAXIS/PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	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)	UN UNK 2011	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		UN UNK 2011
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

Name of Medication PNEUMONIA VACCINE

Prophylaxis Yes ☒
No ☐

Indication PNEUMONIA
PROPHYLAXIS/PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 05 Apr 2021 18:39:58

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	Intraocular	<input type="radio"/>
	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	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)		UN UNK 2015
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

Name of Medication HERPES ZOSTER VACCINE

Prophylaxis Yes ☒
No ☐

Indication HERPES ZOSTER
PROPHYLAXIS/PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 05 Apr 2021 18:39:58

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Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA
PROPHYLAXIS/PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 05 Apr 2021 18:39:58

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Name of Medication CORTICOSTEROID INJECTION

Prophylaxis Yes ☐
No ☒

Indication CARPAL TUNNEL SYNDROME
LEFT WRIST

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication RIGHT LOWER ABDOMINAL PAIN

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

	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)		28 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

Name of Medication AMOXICILLIN/CLAVULANIC ACID

Prophylaxis Yes ☒
No ☐

Indication POST SURGICAL INFECTION PREVENTION

Dose per administration 875/125

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

	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)	07 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)	10 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

Name of Medication PIPERACILLIN-TAZOBACTAM

Prophylaxis Yes ☐
No ☒

Indication APPENDICITIS

Dose per administration 3375

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

	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)		02 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)		03 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		14 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		14 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

Name of Medication HYDRALAZINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

	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 checked="" type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		02 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		05 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"/>

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

Name of Medication LACTATED RINGERS

Prophylaxis Yes ☐
No ☒

Indication KEEP VEIN OPEN FOR IV
MEDICATIONS

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

	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 checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	02 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)	05 SEP 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"/>

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

Name of Medication MORPHINE

Prophylaxis Yes ☐
No ☒

Indication RIGHT LOWER ABDOMINAL PAIN

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

	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 checked="" type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	02 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		05 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"/>

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

Name of Medication OXYCODONE/ACETAMINOPHE
N 5/325

Prophylaxis Yes ☐
No ☒

Indication RIGHT LOWER ABDOMINAL
PAIN

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)

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US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	02 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		05 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"/>

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

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)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

	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 checked="" type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	02 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	05 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"/>

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

Name of Medication ZOFRAN

Prophylaxis Yes ☐
No ☒

Indication NAUSEA

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 05 Apr 2021 18:39:58

Generated On: 09 Jun 2021 17:14:43

	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 checked="" type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		02 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		05 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"/>

US3372184

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 16 Feb 2021 18:08:43

Generated On: 09 Jun 2021 17:14:43

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3372184

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 16 Feb 2021 18:08:43

Generated On: 09 Jun 2021 17:14:43

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
2 SEP 2020	APPENDECTOMY	Adverse Event	

US3372184

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:14:43

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

US3372184

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:14:43

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 ☐

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 16 Mar 2021 19:21:43

Generated On: 09 Jun 2021 17:14:43

SAEID	USA-US056-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 16 Mar 2021 19:21:43

Generated On: 09 Jun 2021 17:14:43

SAEID	USA-US056-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	07/SEP/2020 12:55
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

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 16 Mar 2021 19:21:43

Generated On: 09 Jun 2021 17:14:43

SAEID	USA-US056-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	20/OCT/2020 15:17
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

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) 16 Mar 2021 19:21:43

Generated On: 09 Jun 2021 17:14:43

SAEID	USA-US056-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	27/OCT/2020 08:46
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

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Data signed: (b) (4) 16 Mar 2021 19:21:43

Generated On: 09 Jun 2021 17:14:43

SAEID	USA-US056-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	03/NOV/2020 18:09
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Data signed: (b) (4) 16 Mar 2021 19:21:43

Generated On: 09 Jun 2021 17:14:43

SAEID	USA-US056-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	11/NOV/2020 14:08
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

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Data signed: (b) (4) 16 Mar 2021 19:21:43

Generated On: 09 Jun 2021 17:14:43

SAEID	USA-US056-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	26/FEB/2021 03:07
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

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form (7)

Data signed: (b) (4) 16 Mar 2021 19:21:43

Generated On: 09 Jun 2021 17:14:43

SAEID	USA-US056-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MIRA
Investigator's Last Name	BARON
Site Address: Street	2277 PALM BEACH LAKES BLVD
Site Address: City	WEST PALM BEACH
Site Address: State	
Site Address: Postal Code	33409
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	08/MAR/2021 11:12
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

Audit

US3372184 (Prod: Palm Beach Research Center)

US3372184

Form: Participant Creation

Generated On: 09 Jun 2021 17:14:43

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:42:17
User entered 'US3372184'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 18:14:21

US3372184

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:14:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:11:53
User entered 'Yes (Y)'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:46:36

US3372184

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:11:53
User entered '19 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 18:14:22

US3372184

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:14:43

[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 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:11:53
User entered 'Clinic (Clinic)'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:46:36

US3372184

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:14:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered 'SCRN'	System	19 Aug 2020 19:46:36

US3372184

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:14:43

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:05:28
User entered (b) (6) 1947'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 18:14:23

US3372184

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:14:43

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:05:28
User entered '72'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:47:03

US3372184

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:14:43

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered 'YEARS'	System	19 Aug 2020 19:47:03

US3372184

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:14:43

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered '72'	System	19 Aug 2020 19:47:16

US3372184

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:14:43

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:05:28
User entered 'Male (M)'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:47:03

US3372184

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:14:43

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:05:28
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:47:03

US3372184

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:14:43

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:05:28
User entered 'I'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:47:03

US3372184

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:14:43

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:05:28
User entered '0'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:47:03

US3372184

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:14:43

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:05:28
User entered '0'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:47:03

US3372184

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:14:43

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:05:28
User entered '0'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:47:03

US3372184

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:14:43

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:05:28
User entered '0'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:47:03

US3372184

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:14:43

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:05:28
User entered '0'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:47:03

US3372184

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:14:43

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:05:28
User entered empty.	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:47:03

US3372184

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:14:43

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:05:28
User entered '0'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:47:03

US3372184

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:14:43

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:05:28
User entered '0'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:47:03

US3372184

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:14:43

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:24:17
User entered '19 Aug 2020'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:47:16

US3372184

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered 'Aug 2020'	System	19 Aug 2020 19:47:16

US3372184

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered '2020'	System	19 Aug 2020 19:47:16

US3372184

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:14:43

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:24:17
User entered 'Amendment 2 (2)'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:47:16

US3372184

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:24:17
User entered 'Yes (Y)'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:47:16

US3372184

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:24:17
User entered empty.	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:47:16

US3372184

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:14:43

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:24:17
User entered empty.	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:47:16

US3372184

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:14:43

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:24:17
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:47:16

US3372184

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:14:43

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:24:17
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 18:14:22

US3372184

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:14:43

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered 'I'	System	19 Aug 2020 19:47:22

US3372184

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:18:03
User entered 'Yes (Y)'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:47:22

US3372184

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:14:43

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:50:17
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	14 Oct 2020 18:36:52

US3372184

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:14:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
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)	14 Oct 2020 18:48:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 18:48:41
Data point term sent to Coder	System	14 Oct 2020 18:47:09
User entered 'gastroesophageal reflux disease'	Peter Jacob (b) (4)	14 Oct 2020 18:46:34

US3372184

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered 'un UNK 2009'	(b) (4) Peter Jacob (b) (4)	14 Oct 2020 18:46:34

US3372184

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:14:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:46:34

US3372184

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:14:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	14 Oct 2020 18:46:34

US3372184

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:46:34

US3372184

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:14:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:46:34

US3372184

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered 'Jan 2009'	System	14 Oct 2020 18:46:34

US3372184

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered '2009'	System	14 Oct 2020 18:46:34

US3372184

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered empty.	System	14 Oct 2020 18:46:34

US3372184

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered empty.	System	14 Oct 2020 18:46:34

US3372184

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:14:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User coded data point as SOC: Nervous system disorders, HLGT: Movement disorders (incl parkinsonism), HLT: Tremor (excl congenital), PT: Essential tremor, LLT: Essential tremor - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 18:48:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 18:48:42
Data point term sent to Coder	System	14 Oct 2020 18:47:10
User entered 'essential tremors'	Peter Jacob (b) (4)	14 Oct 2020 18:46:46

US3372184

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered 'un UNK 1997'	(b) (4) Peter Jacob (b) (4)	14 Oct 2020 18:46:46

US3372184

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:14:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:46:46

US3372184

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:14:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:46:46

US3372184

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:46:46

US3372184

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:14:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:46:46

US3372184

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered 'Jan 1997'	System	14 Oct 2020 18:46:46

US3372184

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered '1997'	System	14 Oct 2020 18:46:46

US3372184

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered empty.	System	14 Oct 2020 18:46:46

US3372184

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered empty.	System	14 Oct 2020 18:46:46

US3372184

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:14:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hyperplasia - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 18:48:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 18:48:41
Data point term sent to Coder	System	14 Oct 2020 18:47:10
User entered 'benign prostatic hyperplasia (BPH)'	Peter Jacob (b) (4)	14 Oct 2020 18:47:05

US3372184

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered 'un UNK 2019'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:47:05

US3372184

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:14:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:47:05

US3372184

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:14:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	14 Oct 2020 18:47:05

US3372184

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:47:05

US3372184

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:14:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:47:05

US3372184

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered 'Jan 2019'	System	14 Oct 2020 18:47:05

US3372184

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered '2019'	System	14 Oct 2020 18:47:05

US3372184

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered empty.	System	14 Oct 2020 18:47:05

US3372184

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered empty.	System	14 Oct 2020 18:47:05

US3372184

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:14:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Urinary retention, LLT: Urinary retention - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 18:49:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 18:49:32
Data point term sent to Coder	System	14 Oct 2020 18:48:11
User entered 'urinary retention'	Peter Jacob (b) (4)	14 Oct 2020 18:47:24

US3372184

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered 'un UNK 2019'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:47:24

US3372184

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:14:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:47:24

US3372184

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:14:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:47:24

US3372184

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:47:24

US3372184

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:14:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:47:24

US3372184

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered 'Jan 2019'	System	14 Oct 2020 18:47:24

US3372184

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered '2019'	System	14 Oct 2020 18:47:24

US3372184

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered empty.	System	14 Oct 2020 18:47:24

US3372184

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered empty.	System	14 Oct 2020 18:47:24

US3372184

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:14:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 18:49:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 18:49:31
Data point term sent to Coder	System	14 Oct 2020 18:48:11
User entered 'hypertension'	Peter Jacob (b) (4)	14 Oct 2020 18:47:37

US3372184

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered 'un UNK 1970'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:47:37

US3372184

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:14:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:47:37

US3372184

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:14:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:47:37

US3372184

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:47:37

US3372184

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:14:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:47:37

US3372184

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered 'Jan 1970'	System	14 Oct 2020 18:47:37

US3372184

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered '1970'	System	14 Oct 2020 18:47:37

US3372184

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered empty.	System	14 Oct 2020 18:47:37

US3372184

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered empty.	System	14 Oct 2020 18:47:37

US3372184

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:14:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 18:49:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 18:49:31
Data point term sent to Coder	System	14 Oct 2020 18:48:11
User entered 'hypercholesterolemia'	Peter Jacob (b) (4)	14 Oct 2020 18:47:47

US3372184

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered 'un UNK 2005'	(b) (4) Peter Jacob (b) (4)	14 Oct 2020 18:47:47

US3372184

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:14:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:47:47

US3372184

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:14:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	14 Oct 2020 18:47:47

US3372184

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:47:47

US3372184

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:14:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:47:47

US3372184

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered 'Jan 2005'	System	14 Oct 2020 18:47:47

US3372184

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered '2005'	System	14 Oct 2020 18:47:47

US3372184

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered empty.	System	14 Oct 2020 18:47:47

US3372184

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered empty.	System	14 Oct 2020 18:47:47

US3372184

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:14:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 18:49:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 18:49:32
Data point term sent to Coder	System	14 Oct 2020 18:48:11
User entered 'anxiety'	Peter Jacob (b) (4)	14 Oct 2020 18:47:55

US3372184

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered 'un UNK 1974'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:47:55

US3372184

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:14:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:47:55

US3372184

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:14:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:47:55

US3372184

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:47:55

US3372184

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:14:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:47:55

US3372184

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered 'Jan 1974'	System	14 Oct 2020 18:47:55

US3372184

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered '1974'	System	14 Oct 2020 18:47:55

US3372184

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered empty.	System	14 Oct 2020 18:47:55

US3372184

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered empty.	System	14 Oct 2020 18:47:55

US3372184

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:14:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Sinusitis, LLT: Sinusitis - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 18:49:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 18:49:31
Data point term sent to Coder	System	14 Oct 2020 18:48:12
User entered 'sinusitis'	Peter Jacob (b) (4)	14 Oct 2020 18:48:04

US3372184

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered 'un UNK 1994'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:48:04

US3372184

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:14:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:48:04

US3372184

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:14:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	14 Oct 2020 18:48:04

US3372184

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:48:04

US3372184

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:14:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:48:04

US3372184

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered 'Jan 1994'	System	14 Oct 2020 18:48:04

US3372184

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered '1994'	System	14 Oct 2020 18:48:04

US3372184

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered empty.	System	14 Oct 2020 18:48:04

US3372184

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered empty.	System	14 Oct 2020 18:48:04

US3372184

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:14:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Hypersensitivity, LLT: Environmental allergy - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 18:50:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 18:50:37
Data point term sent to Coder	System	14 Oct 2020 18:49:12
User entered 'allergy - environmental'	Peter Jacob (b) (4)	14 Oct 2020 18:48:20

US3372184

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered 'un UNK 1994'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:48:20

US3372184

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:14:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:48:20

US3372184

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:14:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	14 Oct 2020 18:48:20

US3372184

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:48:20

US3372184

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:14:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:48:20

US3372184

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered 'Jan 1994'	System	14 Oct 2020 18:48:20

US3372184

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered '1994'	System	14 Oct 2020 18:48:20

US3372184

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered empty.	System	14 Oct 2020 18:48:20

US3372184

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered empty.	System	14 Oct 2020 18:48:20

US3372184

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:14:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Genital herpes, LLT: Genital herpes - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 18:50:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 18:50:37
Data point term sent to Coder	System	14 Oct 2020 18:49:14
User entered 'genital herpes'	Peter Jacob (b) (4)	14 Oct 2020 18:48:29

US3372184

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered 'un UNK 1958'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:48:29

US3372184

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:14:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:48:29

US3372184

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:14:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	14 Oct 2020 18:48:29

US3372184

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:48:29

US3372184

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:14:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:48:29

US3372184

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered 'Jan 1958'	System	14 Oct 2020 18:48:29

US3372184

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered '1958'	System	14 Oct 2020 18:48:29

US3372184

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered empty.	System	14 Oct 2020 18:48:29

US3372184

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered empty.	System	14 Oct 2020 18:48:29

US3372184

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:14:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User coded data point as SOC: Reproductive system and breast disorders, HLGT: 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)	14 Oct 2020 18:50:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 18:50:38
Data point term sent to Coder	System	14 Oct 2020 18:49:14
User entered 'erectile dysfunction'	Peter Jacob (b) (4)	14 Oct 2020 18:48:41

US3372184

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered 'un UNK 1999'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:48:41

US3372184

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:14:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:48:41

US3372184

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:14:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	14 Oct 2020 18:48:41

US3372184

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:48:41

US3372184

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:14:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:48:41

US3372184

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered 'Jan 1999'	System	14 Oct 2020 18:48:41

US3372184

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered '1999'	System	14 Oct 2020 18:48:41

US3372184

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered empty.	System	14 Oct 2020 18:48:41

US3372184

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered empty.	System	14 Oct 2020 18:48:41

US3372184

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:14:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Generalized osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 18:50:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 18:50:38
Data point term sent to Coder	System	14 Oct 2020 18:49:15
User entered 'generalized osteoarthritis'	Peter Jacob (b) (4)	14 Oct 2020 18:48:53

US3372184

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered 'un UNK 1995'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:48:53

US3372184

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:14:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:48:53

US3372184

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:14:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	14 Oct 2020 18:48:53

US3372184

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:48:53

US3372184

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:14:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:48:53

US3372184

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered 'Jan 1995'	System	14 Oct 2020 18:48:53

US3372184

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered '1995'	System	14 Oct 2020 18:48:53

US3372184

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered empty.	System	14 Oct 2020 18:48:53

US3372184

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered empty.	System	14 Oct 2020 18:48:53

US3372184

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:14:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal vascular conditions, HLT: Haemorrhoids and gastrointestinal varices (excl oesophageal), PT: Haemorrhoids, LLT: Internal hemorrhoids - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 18:50:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 18:50:38
Data point term sent to Coder	System	14 Oct 2020 18:49:16
User entered 'internal hemorrhoids'	Peter Jacob (b) (4)	14 Oct 2020 18:49:05

US3372184

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered 'un UNK 2019'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:49:05

US3372184

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:14:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:49:05

US3372184

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:14:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	14 Oct 2020 18:49:05

US3372184

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:49:05

US3372184

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:14:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:49:05

US3372184

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered 'Jan 2019'	System	14 Oct 2020 18:49:05

US3372184

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered '2019'	System	14 Oct 2020 18:49:05

US3372184

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered empty.	System	14 Oct 2020 18:49:05

US3372184

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered empty.	System	14 Oct 2020 18:49:05

US3372184

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:14:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteopenia, LLT: Osteopenia - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 18:51:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 18:51:40
Data point term sent to Coder	System	14 Oct 2020 18:50:17
User entered 'osteopenia'	Peter Jacob (b) (4)	14 Oct 2020 18:49:22

US3372184

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered 'un UNK 1999'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:49:22

US3372184

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:14:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:49:22

US3372184

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:14:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	14 Oct 2020 18:49:22

US3372184

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:49:22

US3372184

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:14:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:49:22

US3372184

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered 'Jan 1999'	System	14 Oct 2020 18:49:22

US3372184

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered '1999'	System	14 Oct 2020 18:49:22

US3372184

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered empty.	System	14 Oct 2020 18:49:22

US3372184

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered empty.	System	14 Oct 2020 18:49:22

US3372184

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:14:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Mononeuropathies, PT: Carpal tunnel syndrome, LLT: Unilateral carpal tunnel syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 05:23:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 05:23:21
Data point term sent to Coder	System	14 Oct 2020 18:50:18
User entered 'carpal tunnel syndrome left wrist '	Peter Jacob (b) (4)	14 Oct 2020 18:49:37

US3372184

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered 'un UNK 2017'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:49:37

US3372184

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:14:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:49:37

US3372184

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:14:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	14 Oct 2020 18:49:37

US3372184

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:49:37

US3372184

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:14:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:49:37

US3372184

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered 'Jan 2017'	System	14 Oct 2020 18:49:37

US3372184

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered '2017'	System	14 Oct 2020 18:49:37

US3372184

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered empty.	System	14 Oct 2020 18:49:37

US3372184

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered empty.	System	14 Oct 2020 18:49:37

US3372184

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:14:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Bilateral cataracts - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	14 Oct 2020 18:51:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 18:51:41
Data point term sent to Coder	System	14 Oct 2020 18:50:19
User entered 'cataracts bilateral'	Peter Jacob (b) (4)	14 Oct 2020 18:49:56
	(b) (4)	

US3372184

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered 'un UNK 2013'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:49:56

US3372184

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:14:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:49:56

US3372184

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:14:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:49:56

US3372184

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered 'un UNK 2013'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:49:56

US3372184

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:14:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:49:56

US3372184

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered 'Jan 2013'	System	14 Oct 2020 18:49:56

US3372184

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered '2013'	System	14 Oct 2020 18:49:56

US3372184

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered 'Jan 2013'	System	14 Oct 2020 18:49:56

US3372184

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered '2013'	System	14 Oct 2020 18:49:56

US3372184

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:14:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Cataract operation, LLT: Cataract operation - version MedDRA\\23.0.	Coder Import (b) (4)	24 Oct 2020 23:46:35
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4)	24 Oct 2020 23:46:35
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Cataract operation, LLT: Bilateral cataract extraction - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 18:52:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 18:52:33
Data point term sent to Coder	System	14 Oct 2020 18:51:24
User entered 'caTARACTS surgery bilateral'	Peter Jacob (b) (4)	14 Oct 2020 18:50:52

US3372184

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered 'un UNK 2013'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:50:52

US3372184

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:14:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:50:52

US3372184

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:14:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:50:52

US3372184

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered 'un UNK 2013'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:50:52

US3372184

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:14:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:50:52

US3372184

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered 'Jan 2013'	System	14 Oct 2020 18:50:52

US3372184

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered '2013'	System	14 Oct 2020 18:50:52

US3372184

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered 'Jan 2013'	System	14 Oct 2020 18:50:52

US3372184

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered '2013'	System	14 Oct 2020 18:50:52

US3372184

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:14:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Cerebral injuries NEC, PT: Subdural haematoma, LLT: Subdural hematoma - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 18:52:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 18:52:33
Data point term sent to Coder	System	14 Oct 2020 18:51:24
User entered 'subdural hematoma'	Peter Jacob (b) (4)	14 Oct 2020 18:51:08

US3372184

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered 'un UNK 2007'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:51:08

US3372184

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:14:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:51:08

US3372184

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:14:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	14 Oct 2020 18:51:08

US3372184

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered 'un UNK 2007'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:51:08

US3372184

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:14:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:51:08

US3372184

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered 'Jan 2007'	System	14 Oct 2020 18:51:08

US3372184

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered '2007'	System	14 Oct 2020 18:51:08

US3372184

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered 'Jan 2007'	System	14 Oct 2020 18:51:08

US3372184

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered '2007'	System	14 Oct 2020 18:51:08

US3372184

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:14:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Skull and brain therapeutic procedures, PT: Craniotomy, LLT: Burr hole - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 18:52:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 18:52:33
Data point term sent to Coder	System	14 Oct 2020 18:51:24
User entered 'burr hole'	Peter Jacob (b) (4)	14 Oct 2020 18:51:24

US3372184

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered 'un UNK 2007'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:51:24

US3372184

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:14:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:51:24

US3372184

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:14:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	14 Oct 2020 18:51:24

US3372184

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered 'un UNK 2007'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:51:24

US3372184

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:14:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:51:24

US3372184

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered 'Jan 2007'	System	14 Oct 2020 18:51:24

US3372184

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered '2007'	System	14 Oct 2020 18:51:24

US3372184

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered 'Jan 2007'	System	14 Oct 2020 18:51:24

US3372184

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered '2007'	System	14 Oct 2020 18:51:24

US3372184

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:14:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Upper respiratory tract disorders (excl infections), HLT: Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms), PT: Vocal cord polyp, LLT: Vocal cord polyp - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 18:53:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 18:53:36
Data point term sent to Coder	System	14 Oct 2020 18:52:27
User entered 'vocal cord polyps'	Peter Jacob (b) (4)	14 Oct 2020 18:52:11

US3372184

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered 'un UNK 2005'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:52:11

US3372184

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:14:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:52:11

US3372184

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:14:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	14 Oct 2020 18:52:11

US3372184

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered 'un UNK 2005'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:52:11

US3372184

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:14:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:52:11

US3372184

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered 'Jan 2005'	System	14 Oct 2020 18:52:11

US3372184

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered '2005'	System	14 Oct 2020 18:52:11

US3372184

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered 'Jan 2005'	System	14 Oct 2020 18:52:11

US3372184

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered '2005'	System	14 Oct 2020 18:52:11

US3372184

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:14:43

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Laryngeal therapeutic procedures, PT: Vocal cord polypectomy, LLT: Vocal cord polypectomy - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 18:54:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 18:54:31
Data point term sent to Coder	System	14 Oct 2020 18:53:29
User entered 'vocal cord polypectomy'	Peter Jacob (b) (4)	14 Oct 2020 18:52:28

US3372184

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered 'un UNK 2005'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:52:28

US3372184

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:14:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:52:28

US3372184

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:14:43

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	14 Oct 2020 18:52:28

US3372184

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered 'un UNK 2005'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:52:28

US3372184

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:14:43

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:34:04
User entered '0'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:52:28

US3372184

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered 'Jan 2005'	System	14 Oct 2020 18:52:28

US3372184

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered '2005'	System	14 Oct 2020 18:52:28

US3372184

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered 'Jan 2005'	System	14 Oct 2020 18:52:28

US3372184

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered '2005'	System	14 Oct 2020 18:52:28

US3372184

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:28:17
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	27 Aug 2020 17:21:18

US3372184

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:28:17
User entered '19 Aug 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	27 Aug 2020 17:21:18

US3372184

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:28:17
User entered '15:00'	(b) (4) Peter Jacob (b) (4) (b) (4)	27 Aug 2020 17:21:18

US3372184

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered '19 Aug 2020 15:00'	System	27 Aug 2020 17:21:18

US3372184

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:28:17
User entered '162.6' cm	(b) (4) Peter Jacob (b) (4)	27 Aug 2020 17:21:18
DataPoint set to visible.	(b) (4) System	19 Aug 2020 19:47:22

US3372184

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:28:17
User entered '59.6' kg	(b) (4) Peter Jacob (b) (4)	27 Aug 2020 17:21:18
DataPoint set to visible.	(b) (4) System	19 Aug 2020 19:47:22

US3372184

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
Amendment Manager: User entered '22.54266'	System	17 Sep 2020 00:14:35
User entered '22.5'	System	27 Aug 2020 17:21:18
DataPoint set to visible.	System	19 Aug 2020 19:47:22

US3372184

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered 'kg/m2'	System	27 Aug 2020 17:21:18
DataPoint set to visible.	System	19 Aug 2020 19:47:22

US3372184

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:28:17
User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. For Visit 1 Day 1 Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 05:32:06
Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. For Visit 1 Day 1 Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly.' answered with 'done' (Site from DM).	Peter Jacob (b) (4) (b) (4)	25 Sep 2020 17:36:55
Un-reviewed for Data Management.	Peter Jacob (b) (4) (b) (4)	25 Sep 2020 17:36:40
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4) (b) (4)	25 Sep 2020 17:36:40
User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dosed on the same day; screening vitals should only capture the response to "Were vital signs assessed", date, time, height and weight. All other enterable data fields should be recorded as ND. For Visit 1 Day 1 Vital Signs-Dosing should be completed except for the HT and WT, these should be recorded as ND. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 13:35:23
Reviewed for Data Management.	(b) (4), (b) (6)	22 Sep 2020 13:35:11

US3372184

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.4' C	Peter Jacob (b) (4) (b) (4)	27 Aug 2020 17:21:18

US3372184

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:28:17
User entered empty; reason for change Data Entry Error	(b) (4)	
	Peter Jacob (b) (4)	25 Sep 2020 17:36:40
User entered 'Oral (Oral)'	(b) (4)	
	Peter Jacob (b) (4)	27 Aug 2020 17:21:18
	(b) (4)	

US3372184

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:28:17
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	27 Aug 2020 17:21:18

US3372184

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:28:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 17:36:40
User entered '52'	Peter Jacob (b) (4)	27 Aug 2020 17:21:18
	(b) (4)	

US3372184

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered 'bpm'	System	27 Aug 2020 17:21:18

US3372184

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:28:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 17:36:40
User entered '18'	Peter Jacob (b) (4)	27 Aug 2020 17:21:18
	(b) (4)	

US3372184

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered 'breaths/min'	System	27 Aug 2020 17:21:18

US3372184

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:28:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 17:36:40
User entered '152'	Peter Jacob (b) (4)	27 Aug 2020 17:21:18
	(b) (4)	

US3372184

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered 'mmHg'	System	27 Aug 2020 17:21:18

US3372184

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:28:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Sep 2020 17:36:40
User entered '88'	Peter Jacob (b) (4)	27 Aug 2020 17:21:18
	(b) (4)	

US3372184

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User entered 'mmHg'	System	27 Aug 2020 17:21:18

US3372184

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59

US3372184

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59

US3372184

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:14:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:05:56
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	27 Aug 2020 17:21:25

US3372184

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:14:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:05:56
User entered '19 Aug 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	27 Aug 2020 17:21:25

US3372184

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:43

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 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:16:14
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:10

US3372184

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:43

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 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:16:14
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:10

US3372184

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:43

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 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:16:14
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:10

US3372184

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:43

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 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:16:14
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:10

US3372184

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:43

[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 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:16:14
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:10

US3372184

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:43

[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 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:16:14
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:10

US3372184

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:43

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 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:16:14
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:10

US3372184

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:43

[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 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:16:14
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:10

US3372184

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:43

[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 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:16:14
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:10

US3372184

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:43

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 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:16:14
User entered 'Yes (Y)'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:10

US3372184

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:43

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 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:16:14
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:10

US3372184

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:43

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:16:14
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:10

US3372184

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:43

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:16:14
User entered empty.	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:10

US3372184

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:43

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:16:14
User entered '0'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:10

US3372184

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:43

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:16:14
User entered '0'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:10

US3372184

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:43

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 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:16:14
User entered '0'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:10

US3372184

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:43

[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 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:16:14
User entered 'I'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:10

US3372184

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:43

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 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:16:14
User entered '0'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:10

US3372184

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:43

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:16:14
User entered '0'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:10

US3372184

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:43

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:16:14
User entered '0'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:10

US3372184

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:14:43

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 01:00:59
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:16:14
User entered empty.	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:10

US3372184

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:14:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:11:53
User entered 'Yes (Y)'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:22

US3372184

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:11:53
User entered '19 Aug 2020'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:22

US3372184

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:11:53
User entered 'Clinic (Clinic)'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:22

US3372184

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:14:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User entered 'VISIT1'	System	19 Aug 2020 19:48:22

US3372184

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:59:31
User entered '19 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 19:40:31

US3372184

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:14:43

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:59:31
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 05:39:25
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:39:25
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Aug 2020 19:40:31
User entered '187082' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 19:40:31

US3372184

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:14:43

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:59:31
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 19:40:31

US3372184

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:14:43

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:59:31
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:48

US3372184

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:14:43

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:59:31
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:48

US3372184

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:14:43

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:59:31
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:48

US3372184

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:14:43

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:59:31
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:48

US3372184

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:14:43

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:59:31
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:48

US3372184

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:14:43

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:59:31
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	14 Oct 2020 18:54:06
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 10:36:05
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:35:03

US3372184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:14:43

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 12:27:31
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.'	Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:15:40
answered with 'data updated' (Site from DM).		
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:15:13
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 14:03:26
User entered '162.6' cm	Peter Jacob (b) (4) (b) (4)	27 Aug 2020 17:22:57

US3372184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:14:43

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	29 Sep 2020 15:15:13
User entered '59.6' kg	Peter Jacob (b) (4)	27 Aug 2020 17:22:57
	(b) (4)	

US3372184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:14:43

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 12:27:31
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' answered with 'data updated' (Site from DM).	Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:15:40
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:15:13
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 14:03:26
User entered '162.6' cm	Peter Jacob (b) (4) (b) (4)	27 Aug 2020 17:22:57

US3372184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:14:43

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	29 Sep 2020 15:15:13
User entered '59.6' kg	Peter Jacob (b) (4)	27 Aug 2020 17:22:57
	(b) (4)	

US3372184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User accepted default value 'Pre-Dose (PREDOSE)'	Peter Jacob (b) (4) (b) (4)	27 Aug 2020 17:22:57

US3372184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	27 Aug 2020 17:22:57

US3372184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered '19 Aug 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	27 Aug 2020 17:22:57

US3372184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered '15:00'	(b) (4) Peter Jacob (b) (4) (b) (4)	27 Aug 2020 17:22:57

US3372184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User entered '19 Aug 2020 15:00'	System	27 Aug 2020 17:22:57

US3372184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered '36.4' C	(b) (4) Peter Jacob (b) (4)	27 Aug 2020 17:22:57

US3372184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered 'Oral (Oral)'	(b) (4) Peter Jacob (b) (4) (b) (4)	27 Aug 2020 17:22:57

US3372184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	27 Aug 2020 17:22:57

US3372184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered '52'	(b) (4) Peter Jacob (b) (4) (b) (4)	27 Aug 2020 17:22:57

US3372184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User entered 'bpm'	System	27 Aug 2020 17:22:57

US3372184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered '18'	(b) (4) Peter Jacob (b) (4) (b) (4)	27 Aug 2020 17:22:57

US3372184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User entered 'breaths/min'	System	27 Aug 2020 17:22:57

US3372184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered '152'	(b) (4) Peter Jacob (b) (4) (b) (4)	27 Aug 2020 17:22:57

US3372184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User entered 'mmHg'	System	27 Aug 2020 17:22:57

US3372184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered '88'	(b) (4) Peter Jacob (b) (4) (b) (4)	27 Aug 2020 17:22:57

US3372184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User entered 'mmHg'	System	27 Aug 2020 17:22:57

US3372184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:14:43

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 12:27:31
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.'	Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:15:40
answered with 'data updated' (Site from DM).		
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4) (b) (4)	29 Sep 2020 15:15:13
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 14:03:26
User entered '162.6' cm	Peter Jacob (b) (4) (b) (4)	27 Aug 2020 17:22:57

US3372184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:14:43

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	29 Sep 2020 15:15:13
User entered '59.6' kg	Peter Jacob (b) (4)	27 Aug 2020 17:22:57
	(b) (4)	

US3372184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User accepted default value 'Post-Dose (POSTDOSE)'	Peter Jacob (b) (4) (b) (4)	27 Aug 2020 17:23:51

US3372184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	27 Aug 2020 17:23:51

US3372184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered '19 Aug 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	27 Aug 2020 17:23:51

US3372184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered '16:40'	(b) (4) Peter Jacob (b) (4) (b) (4)	27 Aug 2020 17:23:51

US3372184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User entered '19 Aug 2020 16:40'	System	27 Aug 2020 17:23:51

US3372184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered '36.1' C	(b) (4) Peter Jacob (b) (4)	27 Aug 2020 17:23:51

US3372184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered 'Oral (Oral)'	(b) (4) Peter Jacob (b) (4) (b) (4)	27 Aug 2020 17:23:51

US3372184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	27 Aug 2020 17:23:51

US3372184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered '48'	(b) (4) Peter Jacob (b) (4) (b) (4)	27 Aug 2020 17:23:51

US3372184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User entered 'bpm'	System	27 Aug 2020 17:23:51

US3372184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered '18'	(b) (4) Peter Jacob (b) (4) (b) (4)	27 Aug 2020 17:23:51

US3372184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User entered 'breaths/min'	System	27 Aug 2020 17:23:51

US3372184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered '126'	(b) (4) Peter Jacob (b) (4) (b) (4)	27 Aug 2020 17:23:51

US3372184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User entered 'mmHg'	System	27 Aug 2020 17:23:51

US3372184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered '82'	(b) (4) Peter Jacob (b) (4) (b) (4)	27 Aug 2020 17:23:51

US3372184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User entered 'mmHg'	System	27 Aug 2020 17:23:51

US3372184

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:14:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:05:56
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	27 Aug 2020 17:23:57

US3372184

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:14:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:05:56
User entered '19 Aug 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	27 Aug 2020 17:23:57

US3372184

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:14:43

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:39:55
User entered 'Yes (Y)'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 20:11:22

US3372184

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:14:43

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:39:55
User entered empty.	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 20:11:22

US3372184

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:39:55
User entered empty.	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 20:11:22

US3372184

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:14:43

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User entered 'MRNA-1273 OR PLACEBO'	System	19 Aug 2020 20:11:22

US3372184

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:14:43

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:39:55
User entered '19 Aug 2020'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 20:11:22

US3372184

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:14:43

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:39:55
User entered '16:09'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 20:11:22

US3372184

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:14:43

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User entered '19 Aug 2020 16:09'	System	19 Aug 2020 20:11:22

US3372184

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:14:43

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:39:55
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 20:11:22

US3372184

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:14:43

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User entered 'ONCE'	System	19 Aug 2020 20:11:22

US3372184

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:14:43

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User entered 'INTRAMUSCULAR'	System	19 Aug 2020 20:11:22

US3372184

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:01:40
User entered 'Yes (Y)'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:49:47

US3372184

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:01:40
User entered '19 Aug 2020'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:49:47

US3372184

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:43

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:01:40
User entered '15:35'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:49:47

US3372184

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User entered '19 Aug 2020 15:35'	System	19 Aug 2020 19:49:47

US3372184

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:14:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:17:19
User entered '19 Aug 2020'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:49:31

US3372184

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:14:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:49:31

US3372184

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:14:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:17:19
User entered 'Yes (Y)'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:49:31

US3372184

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:14:43

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:17:19
User entered '15:32'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:49:31

US3372184

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:14:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User entered '19 Aug 2020 15:32'	System	19 Aug 2020 19:49:31

US3372184

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:14:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:49:31

US3372184

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:14:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:17:19
User entered 'No (N)'	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:49:31

US3372184

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:14:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:17:19
User entered empty.	(b) (4) Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:49:31

US3372184

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:14:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User entered empty.	System	19 Aug 2020 19:49:31

US3372184

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:14:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:33:34
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	27 Aug 2020 17:24:00

US3372184

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:14:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User entered 'I'	System	27 Aug 2020 17:24:00

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	19 Aug 2020 20:11:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-19T16:49:17', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '065231d8-4b1e-46d4-ab0f-bf8e992ea252' User entered 'Yes (Y)'	System	19 Aug 2020 20:49:42
	System	19 Aug 2020 20:49:42

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-19T16:49:28', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '065231d8-4b1e-46d4-ab0f-bf8e992ea252' User entered '97.0'	System	19 Aug 2020 20:49:42
	System	19 Aug 2020 20:49:42

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-19T16:49:35', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '065231d8-4b1e-46d4-ab0f-bf8e992ea252'	System	19 Aug 2020 20:49:42
User entered 'No (N)'	System	19 Aug 2020 20:49:42

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-19T16:49:40', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '065231d8-4b1e-46d4-ab0f-bf8e992ea252'	System	19 Aug 2020 20:49:42
User entered '19 Aug 2020 16:49'	System	19 Aug 2020 20:49:42

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '19 Aug 2020 16:29'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '19 Aug 2020 18:59'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	19 Aug 2020 20:11:22
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-20T05:50:15', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '94cfc9ac-8c25-4f68-95e9-18b59718f500' User entered 'Yes (Y)'	System	20 Aug 2020 09:50:37
	System	20 Aug 2020 09:50:37

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-20T05:50:23', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '94cfc9ac-8c25-4f68-95e9-18b59718f500' User entered '97.5'	System	20 Aug 2020 09:50:37
	System	20 Aug 2020 09:50:37

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-20T05:50:29', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '94cfc9ac-8c25-4f68-95e9-18b59718f500'	System	20 Aug 2020 09:50:37
User entered 'No (N)'	System	20 Aug 2020 09:50:37

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-20T05:50:36', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '94cfc9ac-8c25-4f68-95e9-18b59718f500'	System	20 Aug 2020 09:50:37
User entered '20 Aug 2020 05:50'	System	20 Aug 2020 09:50:37

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '19 Aug 2020 19:54'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	19 Aug 2020 20:11:22
User entered 'Day 2'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:14:43

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-20T17:06:02', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '856ad292-e758-4fb2-b3e8-18e963ac04c7' User entered 'Yes (Y)'	System	20 Aug 2020 21:06:27
	System	20 Aug 2020 21:06:27

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:14:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-20T17:06:16', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '856ad292-e758-4fb2-b3e8-18e963ac04c7' User entered '97.5'	System	20 Aug 2020 21:06:27
	System	20 Aug 2020 21:06:27

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-20T17:06:20', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '856ad292-e758-4fb2-b3e8-18e963ac04c7'	System	20 Aug 2020 21:06:27
User entered 'No (N)'	System	20 Aug 2020 21:06:27

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:14:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-20T17:06:24', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '856ad292-e758-4fb2-b3e8-18e963ac04c7' User entered '20 Aug 2020 17:06'	System	20 Aug 2020 21:06:27
	System	20 Aug 2020 21:06:27

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:14:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:14:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	19 Aug 2020 20:11:22
User entered 'Day 3'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:14:43

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-21T12:26:30', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '2717f87c-4289-4df4-9e1f-a4a29877bfd3' User entered 'Yes (Y)'	System	21 Aug 2020 16:26:58
	System	21 Aug 2020 16:26:58

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:14:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-21T12:26:37', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '2717f87c-4289-4df4-9e1f-a4a29877bfd3' User entered '97.9'	System	21 Aug 2020 16:26:58
	System	21 Aug 2020 16:26:58

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-21T12:26:50', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '2717f87c-4289-4df4-9e1f-a4a29877bfd3'	System	21 Aug 2020 16:26:58
User entered 'No (N)'	System	21 Aug 2020 16:26:58

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:14:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-21T12:26:55', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '2717f87c-4289-4df4-9e1f-a4a29877bfd3' User entered '21 Aug 2020 12:26'	System	21 Aug 2020 16:26:58
	System	21 Aug 2020 16:26:58

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:14:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:14:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	19 Aug 2020 20:11:22
User entered 'Day 4'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:14:43

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-22T12:53:11', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '24eead39-b175-4a2f-ae2d-c10a287d42c2' User entered 'Yes (Y)'	System	22 Aug 2020 16:53:26
	System	22 Aug 2020 16:53:26

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:14:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-22T12:53:16', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '24eead39-b175-4a2f-ae2d-c10a287d42c2' User entered '97.2'	System	22 Aug 2020 16:53:26
	System	22 Aug 2020 16:53:26

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-22T12:53:20', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '24eead39-b175-4a2f-ae2d-c10a287d42c2'	System	22 Aug 2020 16:53:26
User entered 'No (N)'	System	22 Aug 2020 16:53:26

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:14:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-22T12:53:25', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '24eead39-b175-4a2f-ae2d-c10a287d42c2' User entered '22 Aug 2020 12:53'	System	22 Aug 2020 16:53:26
	System	22 Aug 2020 16:53:26

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:14:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:14:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	19 Aug 2020 20:11:22
User entered 'Day 5'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:14:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-23T12:08:20', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '6e6668e2-fffd-41ed-b765-b70313a6ece5' User entered 'Yes (Y)'	System	23 Aug 2020 16:08:39
	System	23 Aug 2020 16:08:39

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:14:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-23T12:08:25', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '6e6668e2-fffd-41ed-b765-b70313a6ece5' User entered '97.9'	System	23 Aug 2020 16:08:39
	System	23 Aug 2020 16:08:39

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-23T12:08:30', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '6e6668e2-fffd-41ed-b765-b70313a6ece5'	System	23 Aug 2020 16:08:39
User entered 'No (N)'	System	23 Aug 2020 16:08:39

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:14:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-23T12:08:35', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '6e6668e2-fffd-41ed-b765-b70313a6ece5' User entered '23 Aug 2020 12:08'	System	23 Aug 2020 16:08:39
	System	23 Aug 2020 16:08:39

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:14:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:14:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	19 Aug 2020 20:11:22
User entered 'Day 6'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:14:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-24T13:26:08', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'dcf9c2cf-48b8-4d14-a20a-4cd684a0aa94' User entered 'Yes (Y)'	System	24 Aug 2020 17:26:22
	System	24 Aug 2020 17:26:22

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:14:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-24T13:26:14', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'dcf9c2cf-48b8-4d14-a20a-4cd684a0aa94' User entered '98.1'	System	24 Aug 2020 17:26:22
	System	24 Aug 2020 17:26:22

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-24T13:26:17', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'dcf9c2cf-48b8-4d14-a20a-4cd684a0aa94'	System	24 Aug 2020 17:26:22
User entered 'No (N)'	System	24 Aug 2020 17:26:22

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:14:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-24T13:26:20', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'dcf9c2cf-48b8-4d14-a20a-4cd684a0aa94' User entered '24 Aug 2020 13:26'	System	24 Aug 2020 17:26:22
	System	24 Aug 2020 17:26:22

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:14:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:14:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	19 Aug 2020 20:11:22
User entered 'Day 7'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:14:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-25T12:10:00', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '45559e0b-1350-4e14-9bcf-c07f5e632eac' User entered 'Yes (Y)'	System	25 Aug 2020 16:10:17
	System	25 Aug 2020 16:10:17

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:14:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-25T12:10:06', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '45559e0b-1350-4e14-9bcf-c07f5e632eac' User entered '98.0'	System	25 Aug 2020 16:10:17
	System	25 Aug 2020 16:10:17

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-25T12:10:09', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '45559e0b-1350-4e14-9bcf-c07f5e632eac'	System	25 Aug 2020 16:10:17
User entered 'No (N)'	System	25 Aug 2020 16:10:17

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:14:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-25T12:10:12', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '45559e0b-1350-4e14-9bcf-c07f5e632eac' User entered '25 Aug 2020 12:10'	System	25 Aug 2020 16:10:17
	System	25 Aug 2020 16:10:17

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:14:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:14:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	19 Aug 2020 20:11:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-19T16:49:50', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '92943adb-2dd4-4cce-adb9-356c210b7e28'	System	19 Aug 2020 20:50:26
User entered 'None (1)'	System	19 Aug 2020 20:50:26

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-19T16:49:54', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '92943adb-2dd4-4cce-adb9-356c210b7e28' User entered 'No (N)'	System	19 Aug 2020 20:50:26
	System	19 Aug 2020 20:50:26

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-19T16:49:59', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '92943adb-2dd4-4cce-adb9-356c210b7e28'	System	19 Aug 2020 20:50:26
User entered 'No (N)'	System	19 Aug 2020 20:50:26

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-19T16:50:03', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '92943adb-2dd4-4cce-adb9-356c210b7e28'	System	19 Aug 2020 20:50:26
User entered 'None (1)'	System	19 Aug 2020 20:50:26

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-19T16:50:08', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '92943adb-2dd4-4cce-adb9-356c210b7e28'	System	19 Aug 2020 20:50:26
User entered '19 Aug 2020 16:50'	System	19 Aug 2020 20:50:26

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '19 Aug 2020 16:29'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '19 Aug 2020 18:59'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	19 Aug 2020 20:11:22
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-20T05:50:51', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '52c7ea92-9495-4ba1-beaa-258b6b621745' User entered 'None (1)'	System	20 Aug 2020 09:51:19
	System	20 Aug 2020 09:51:19

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-20T05:50:55', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '52c7ea92-9495-4ba1-beaa-258b6b621745' User entered 'No (N)'	System	20 Aug 2020 09:51:19
	System	20 Aug 2020 09:51:19

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-20T05:50:59', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '52c7ea92-9495-4ba1-beaa-258b6b621745' User entered 'No (N)'	System	20 Aug 2020 09:51:19
	System	20 Aug 2020 09:51:19

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-20T05:51:09', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '52c7ea92-9495-4ba1-beaa-258b6b621745' User entered 'None (1)'	System	20 Aug 2020 09:51:19
	System	20 Aug 2020 09:51:19

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-20T05:51:15', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '52c7ea92-9495-4ba1-beaa-258b6b621745' User entered '20 Aug 2020 05:51'	System	20 Aug 2020 09:51:19
	System	20 Aug 2020 09:51:19

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '19 Aug 2020 19:54'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	19 Aug 2020 20:11:22
User entered 'Day 2'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:14:43

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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-20T17:06:36', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '1be0f659-272d-4b63-a6d9-1acdf610f003'	System	20 Aug 2020 21:06:51
User entered 'None (1)'	System	20 Aug 2020 21:06:51

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:14:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-20T17:06:40', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '1be0f659-272d-4b63-a6d9-1acdf610f003' User entered 'No (N)'	System	20 Aug 2020 21:06:51
	System	20 Aug 2020 21:06:51

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-20T17:06:43', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '1be0f659-272d-4b63-a6d9-1acdf610f003' User entered 'No (N)'	System	20 Aug 2020 21:06:51
	System	20 Aug 2020 21:06:51

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:14:43

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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-20T17:06:47', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '1be0f659-272d-4b63-a6d9-1acdf610f003'	System	20 Aug 2020 21:06:51
User entered 'None (1)'	System	20 Aug 2020 21:06:51

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:14:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-20T17:06:49', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '1be0f659-272d-4b63-a6d9-1acdf610f003' User entered '20 Aug 2020 17:06'	System	20 Aug 2020 21:06:51
	System	20 Aug 2020 21:06:51

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:14:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:14:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	19 Aug 2020 20:11:22
User entered 'Day 3'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:14:43

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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-21T12:27:07', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '8c2c56fa-2a15-4325-9886-325fa52dfdab' User entered 'None (1)'	System	21 Aug 2020 16:28:00
	System	21 Aug 2020 16:28:00

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:14:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-21T12:27:12', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '8c2c56fa-2a15-4325-9886-325fa52dfdab' User entered 'No (N)'	System	21 Aug 2020 16:28:00
	System	21 Aug 2020 16:28:00

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-21T12:27:23', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '8c2c56fa-2a15-4325-9886-325fa52dfdab' User entered 'No (N)'	System	21 Aug 2020 16:28:00
	System	21 Aug 2020 16:28:00

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:14:43

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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-21T12:27:35', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '8c2c56fa-2a15-4325-9886-325fa52dfdab' User entered 'None (1)'	System	21 Aug 2020 16:28:00
	System	21 Aug 2020 16:28:00

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:14:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-21T12:27:57', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '8c2c56fa-2a15-4325-9886-325fa52dfdab' User entered '21 Aug 2020 12:27'	System	21 Aug 2020 16:28:00
	System	21 Aug 2020 16:28:00

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:14:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:14:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	19 Aug 2020 20:11:22
User entered 'Day 4'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:14:43

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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-22T12:53:30', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '29c3fde0-3c12-426b-b408-4adb188fbeb7' User entered 'None (1)'	System	22 Aug 2020 16:53:49
	System	22 Aug 2020 16:53:49

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:14:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-22T12:53:33', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '29c3fde0-3c12-426b-b408-4adb188fbeb7' User entered 'No (N)'	System	22 Aug 2020 16:53:49
	System	22 Aug 2020 16:53:49

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-22T12:53:40', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '29c3fde0-3c12-426b-b408-4adb188fbeb7' User entered 'No (N)'	System	22 Aug 2020 16:53:49
	System	22 Aug 2020 16:53:49

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:14:43

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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-22T12:53:44', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '29c3fde0-3c12-426b-b408-4adb188fbeb7' User entered 'None (1)'	System	22 Aug 2020 16:53:49
	System	22 Aug 2020 16:53:49

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:14:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-22T12:53:47', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '29c3fde0-3c12-426b-b408-4adb188fbeb7' User entered '22 Aug 2020 12:53'	System	22 Aug 2020 16:53:49
	System	22 Aug 2020 16:53:49

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:14:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:14:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	19 Aug 2020 20:11:22
User entered 'Day 5'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:14:43

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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-23T12:08:47', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '71cf536d-9c6f-4567-b840-ab853e488d56'	System	23 Aug 2020 16:09:04
User entered 'None (1)'	System	23 Aug 2020 16:09:04

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-23T12:08:51', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '71cf536d-9c6f-4567-b840-ab853e488d56'	System	23 Aug 2020 16:09:04
User entered 'No (N)'	System	23 Aug 2020 16:09:04

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-23T12:08:54', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '71cf536d-9c6f-4567-b840-ab853e488d56'	System	23 Aug 2020 16:09:04
User entered 'No (N)'	System	23 Aug 2020 16:09:04

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:14:43

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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-23T12:08:59', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '71cf536d-9c6f-4567-b840-ab853e488d56'	System	23 Aug 2020 16:09:04
User entered 'None (1)'	System	23 Aug 2020 16:09:04

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:14:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-23T12:09:02', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '71cf536d-9c6f-4567-b840-ab853e488d56'	System	23 Aug 2020 16:09:04
User entered '23 Aug 2020 12:09'	System	23 Aug 2020 16:09:04

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:14:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:14:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	19 Aug 2020 20:11:22
User entered 'Day 6'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:14:43

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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-24T13:26:24', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'd68a6df4-171c-457f-a0cf-1798f07b45e3'	System	24 Aug 2020 17:26:41
User entered 'None (1)'	System	24 Aug 2020 17:26:41

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:14:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-24T13:26:27', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'd68a6df4-171c-457f-a0cf-1798f07b45e3' User entered 'No (N)'	System	24 Aug 2020 17:26:41
	System	24 Aug 2020 17:26:41

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-24T13:26:30', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'd68a6df4-171c-457f-a0cf-1798f07b45e3' User entered 'No (N)'	System	24 Aug 2020 17:26:41
	System	24 Aug 2020 17:26:41

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:14:43

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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-24T13:26:36', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'd68a6df4-171c-457f-a0cf-1798f07b45e3' User entered 'None (1)'	System	24 Aug 2020 17:26:41
	System	24 Aug 2020 17:26:41

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:14:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-24T13:26:39', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'd68a6df4-171c-457f-a0cf-1798f07b45e3' User entered '24 Aug 2020 13:26'	System	24 Aug 2020 17:26:41
	System	24 Aug 2020 17:26:41

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:14:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:14:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	19 Aug 2020 20:11:22
User entered 'Day 7'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:14:43

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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-25T12:10:23', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '07c0b67f-ff7c-4457-a5e0-1fa23377360e' User entered 'None (1)'	System	25 Aug 2020 16:10:51
	System	25 Aug 2020 16:10:51

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-25T12:10:27', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '07c0b67f-ff7c-4457-a5e0-1fa23377360e' User entered 'No (N)'	System	25 Aug 2020 16:10:51
	System	25 Aug 2020 16:10:51

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-25T12:10:31', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '07c0b67f-ff7c-4457-a5e0-1fa23377360e' User entered 'No (N)'	System	25 Aug 2020 16:10:51
	System	25 Aug 2020 16:10:51

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:14:43

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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-25T12:10:44', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '07c0b67f-ff7c-4457-a5e0-1fa23377360e' User entered 'None (1)'	System	25 Aug 2020 16:10:51
	System	25 Aug 2020 16:10:51

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:14:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-25T12:10:47', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '07c0b67f-ff7c-4457-a5e0-1fa23377360e' User entered '25 Aug 2020 12:10'	System	25 Aug 2020 16:10:51
	System	25 Aug 2020 16:10:51

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:14:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:14:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	19 Aug 2020 20:11:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-19T16:50:13', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '944a440b-aa26-4caa-9db1-201ec299e2d3' User entered 'None (0)'	System	19 Aug 2020 20:50:39
	System	19 Aug 2020 20:50:39

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-19T16:50:17', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '944a440b-aa26-4caa-9db1-201ec299e2d3' User entered 'None (0)'	System	19 Aug 2020 20:50:39
	System	19 Aug 2020 20:50:39

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-19T16:50:22', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '944a440b-aa26-4caa-9db1-201ec299e2d3' User entered 'None (0)'	System	19 Aug 2020 20:50:39
	System	19 Aug 2020 20:50:39

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-19T16:50:25', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '944a440b-aa26-4caa-9db1-201ec299e2d3' User entered 'None (0)'	System	19 Aug 2020 20:50:39
	System	19 Aug 2020 20:50:39

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-19T16:50:28', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '944a440b-aa26-4caa-9db1-201ec299e2d3' User entered 'None (0)'	System	19 Aug 2020 20:50:39
	System	19 Aug 2020 20:50:39

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-19T16:50:31', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '944a440b-aa26-4caa-9db1-201ec299e2d3' User entered 'None (0)'	System	19 Aug 2020 20:50:39
	System	19 Aug 2020 20:50:39

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-19T16:50:35', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '944a440b-aa26-4caa-9db1-201ec299e2d3' User entered 'No (N)'	System	19 Aug 2020 20:50:39
	System	19 Aug 2020 20:50:39

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-19T16:50:38', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '944a440b-aa26-4caa-9db1-201ec299e2d3'	System	19 Aug 2020 20:50:39
User entered '19 Aug 2020 16:50'	System	19 Aug 2020 20:50:39

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '19 Aug 2020 16:29'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '19 Aug 2020 18:59'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	19 Aug 2020 20:11:22
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-20T05:51:22', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'abb3f9ba-9134-467f-abf7-20ccd441242e' User entered 'None (0)'	System	20 Aug 2020 09:52:16
	System	20 Aug 2020 09:52:16

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-20T05:51:42', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'abb3f9ba-9134-467f-abf7-20ccd441242e' User entered 'None (0)'	System	20 Aug 2020 09:52:16
	System	20 Aug 2020 09:52:16

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-20T05:51:45', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'abb3f9ba-9134-467f-abf7-20ccd441242e' User entered 'None (0)'	System	20 Aug 2020 09:52:16
	System	20 Aug 2020 09:52:16

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-20T05:51:48', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'abb3f9ba-9134-467f-abf7-20ccd441242e' User entered 'None (0)'	System	20 Aug 2020 09:52:16
	System	20 Aug 2020 09:52:16

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-20T05:51:51', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'abb3f9ba-9134-467f-abf7-20ccd441242e' User entered 'None (0)'	System	20 Aug 2020 09:52:16
	System	20 Aug 2020 09:52:16

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-20T05:51:54', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'abb3f9ba-9134-467f-abf7-20ccd441242e' User entered 'None (0)'	System	20 Aug 2020 09:52:16
	System	20 Aug 2020 09:52:16

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-20T05:52:02', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'abb3f9ba-9134-467f-abf7-20ccd441242e' User entered 'No (N)'	System	20 Aug 2020 09:52:16
	System	20 Aug 2020 09:52:16

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-20T05:52:15', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'abb3f9ba-9134-467f-abf7-20ccd441242e' User entered '20 Aug 2020 05:52'	System	20 Aug 2020 09:52:16
	System	20 Aug 2020 09:52:16

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '19 Aug 2020 19:54'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	19 Aug 2020 20:11:22
User entered 'Day 2'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:14:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-20T17:06:54', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '85d1c250-3773-416d-8f9e-33728ac7c39d' User entered 'None (0)'	System	20 Aug 2020 21:07:29
	System	20 Aug 2020 21:07:29

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:14:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-20T17:06:57', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '85d1c250-3773-416d-8f9e-33728ac7c39d' User entered 'None (0)'	System	20 Aug 2020 21:07:29
	System	20 Aug 2020 21:07:29

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:14:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-20T17:07:00', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '85d1c250-3773-416d-8f9e-33728ac7c39d' User entered 'None (0)'	System	20 Aug 2020 21:07:29
	System	20 Aug 2020 21:07:29

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:14:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-20T17:07:03', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '85d1c250-3773-416d-8f9e-33728ac7c39d' User entered 'None (0)'	System	20 Aug 2020 21:07:29
	System	20 Aug 2020 21:07:29

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:14:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-20T17:07:05', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '85d1c250-3773-416d-8f9e-33728ac7c39d' User entered 'None (0)'	System	20 Aug 2020 21:07:29
	System	20 Aug 2020 21:07:29

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:14:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-20T17:07:18', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '85d1c250-3773-416d-8f9e-33728ac7c39d' User entered 'No interference with activity (1)'	System	20 Aug 2020 21:07:29
	System	20 Aug 2020 21:07:29

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:14:43

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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-20T17:07:22', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '85d1c250-3773-416d-8f9e-33728ac7c39d' User entered 'No (N)'	System	20 Aug 2020 21:07:29
	System	20 Aug 2020 21:07:29

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:14:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-20T17:07:27', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '85d1c250-3773-416d-8f9e-33728ac7c39d' User entered '20 Aug 2020 17:07'	System	20 Aug 2020 21:07:29
	System	20 Aug 2020 21:07:29

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:14:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:14:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	19 Aug 2020 20:11:22
User entered 'Day 3'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:14:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-21T12:28:03', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'c81cf4c3-6861-4ca5-b88a-eb01a8f600b9' User entered 'None (0)'	System	21 Aug 2020 16:28:28
	System	21 Aug 2020 16:28:28

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:14:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-21T12:28:06', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'c81cf4c3-6861-4ca5-b88a-eb01a8f600b9' User entered 'None (0)'	System	21 Aug 2020 16:28:28
	System	21 Aug 2020 16:28:28

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:14:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-21T12:28:08', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'c81cf4c3-6861-4ca5-b88a-eb01a8f600b9' User entered 'None (0)'	System	21 Aug 2020 16:28:28
	System	21 Aug 2020 16:28:28

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:14:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-21T12:28:11', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'c81cf4c3-6861-4ca5-b88a-eb01a8f600b9' User entered 'None (0)'	System	21 Aug 2020 16:28:28
	System	21 Aug 2020 16:28:28

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:14:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-21T12:28:13', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'c81cf4c3-6861-4ca5-b88a-eb01a8f600b9' User entered 'None (0)'	System	21 Aug 2020 16:28:28
	System	21 Aug 2020 16:28:28

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:14:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-21T12:28:16', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'c81cf4c3-6861-4ca5-b88a-eb01a8f600b9' User entered 'None (0)'	System	21 Aug 2020 16:28:28
	System	21 Aug 2020 16:28:28

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:14:43

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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-21T12:28:19', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'c81cf4c3-6861-4ca5-b88a-eb01a8f600b9' User entered 'No (N)'	System	21 Aug 2020 16:28:28
	System	21 Aug 2020 16:28:28

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:14:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-21T12:28:24', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'c81cf4c3-6861-4ca5-b88a-eb01a8f600b9' User entered '21 Aug 2020 12:28'	System	21 Aug 2020 16:28:28
	System	21 Aug 2020 16:28:28

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:14:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:14:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	19 Aug 2020 20:11:22
User entered 'Day 4'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:14:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-22T12:53:52', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '0a34f4a4-15ab-49a3-83dd-c9913a2e5534' User entered 'None (0)'	System	22 Aug 2020 16:54:17
	System	22 Aug 2020 16:54:17

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:14:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-22T12:53:56', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '0a34f4a4-15ab-49a3-83dd-c9913a2e5534' User entered 'None (0)'	System	22 Aug 2020 16:54:17
	System	22 Aug 2020 16:54:17

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:14:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-22T12:54:00', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '0a34f4a4-15ab-49a3-83dd-c9913a2e5534' User entered 'None (0)'	System	22 Aug 2020 16:54:17
	System	22 Aug 2020 16:54:17

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:14:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-22T12:54:03', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '0a34f4a4-15ab-49a3-83dd-c9913a2e5534' User entered 'None (0)'	System	22 Aug 2020 16:54:17
	System	22 Aug 2020 16:54:17

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:14:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-22T12:54:05', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '0a34f4a4-15ab-49a3-83dd-c9913a2e5534' User entered 'None (0)'	System	22 Aug 2020 16:54:17
	System	22 Aug 2020 16:54:17

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:14:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-22T12:54:08', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '0a34f4a4-15ab-49a3-83dd-c9913a2e5534' User entered 'None (0)'	System	22 Aug 2020 16:54:17
	System	22 Aug 2020 16:54:17

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:14:43

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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-22T12:54:11', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '0a34f4a4-15ab-49a3-83dd-c9913a2e5534'	System	22 Aug 2020 16:54:17
User entered 'No (N)'	System	22 Aug 2020 16:54:17

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:14:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-22T12:54:15', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '0a34f4a4-15ab-49a3-83dd-c9913a2e5534' User entered '22 Aug 2020 12:54'	System	22 Aug 2020 16:54:17
	System	22 Aug 2020 16:54:17

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:14:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:14:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	19 Aug 2020 20:11:22
User entered 'Day 5'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:14:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-23T12:09:06', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '70875278-3e8c-4fcb-acb4-4b4e8fbc04cb' User entered 'None (0)'	System	23 Aug 2020 16:09:37
	System	23 Aug 2020 16:09:37

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:14:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-23T12:09:11', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '70875278-3e8c-4fcb-acb4-4b4e8fbc04cb' User entered 'None (0)'	System	23 Aug 2020 16:09:37
	System	23 Aug 2020 16:09:37

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:14:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-23T12:09:14', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '70875278-3e8c-4fcb-acb4-4b4e8fbc04cb' User entered 'None (0)'	System	23 Aug 2020 16:09:37
	System	23 Aug 2020 16:09:37

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:14:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-23T12:09:17', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '70875278-3e8c-4fcb-acb4-4b4e8fbc04cb' User entered 'None (0)'	System	23 Aug 2020 16:09:37
	System	23 Aug 2020 16:09:37

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:14:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-23T12:09:21', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '70875278-3e8c-4fcb-acb4-4b4e8fbc04cb' User entered 'None (0)'	System	23 Aug 2020 16:09:37
	System	23 Aug 2020 16:09:37

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:14:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-23T12:09:24', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '70875278-3e8c-4fcb-acb4-4b4e8fbc04cb' User entered 'None (0)'	System	23 Aug 2020 16:09:37
	System	23 Aug 2020 16:09:37

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:14:43

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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-23T12:09:28', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '70875278-3e8c-4fcb-acb4-4b4e8fbc04cb' User entered 'No (N)'	System	23 Aug 2020 16:09:37
	System	23 Aug 2020 16:09:37

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:14:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-23T12:09:33', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '70875278-3e8c-4fcb-acb4-4b4e8fbc04cb' User entered '23 Aug 2020 12:09'	System	23 Aug 2020 16:09:37
	System	23 Aug 2020 16:09:37

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:14:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:14:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	19 Aug 2020 20:11:22
User entered 'Day 6'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:14:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-24T13:26:43', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '3ac7d90e-9b98-4b93-8a20-10929fabe659' User entered 'None (0)'	System	24 Aug 2020 17:27:09
	System	24 Aug 2020 17:27:09

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:14:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-24T13:26:46', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '3ac7d90e-9b98-4b93-8a20-10929fabe659' User entered 'None (0)'	System	24 Aug 2020 17:27:09
	System	24 Aug 2020 17:27:09

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:14:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-24T13:26:48', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '3ac7d90e-9b98-4b93-8a20-10929fabe659' User entered 'None (0)'	System	24 Aug 2020 17:27:09
	System	24 Aug 2020 17:27:09

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:14:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-24T13:26:51', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '3ac7d90e-9b98-4b93-8a20-10929fabe659' User entered 'None (0)'	System	24 Aug 2020 17:27:09
	System	24 Aug 2020 17:27:09

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:14:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-24T13:26:53', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '3ac7d90e-9b98-4b93-8a20-10929fabe659' User entered 'None (0)'	System	24 Aug 2020 17:27:09
	System	24 Aug 2020 17:27:09

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:14:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-24T13:26:56', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '3ac7d90e-9b98-4b93-8a20-10929fabe659' User entered 'None (0)'	System	24 Aug 2020 17:27:09
	System	24 Aug 2020 17:27:09

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:14:43

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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-24T13:27:02', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '3ac7d90e-9b98-4b93-8a20-10929fabe659' User entered 'No (N)'	System	24 Aug 2020 17:27:09
	System	24 Aug 2020 17:27:09

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:14:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-24T13:27:06', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '3ac7d90e-9b98-4b93-8a20-10929fabe659' User entered '24 Aug 2020 13:27'	System	24 Aug 2020 17:27:09
	System	24 Aug 2020 17:27:09

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:14:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:14:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	19 Aug 2020 20:11:22
User entered 'Day 7'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:14:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-25T12:10:52', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'bc33050a-309b-4379-b949-aa25b8c5fb06' User entered 'None (0)'	System	25 Aug 2020 16:11:15
	System	25 Aug 2020 16:11:15

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:14:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-25T12:10:55', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'bc33050a-309b-4379-b949-aa25b8c5fb06' User entered 'None (0)'	System	25 Aug 2020 16:11:15
	System	25 Aug 2020 16:11:15

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:14:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-25T12:10:57', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'bc33050a-309b-4379-b949-aa25b8c5fb06' User entered 'None (0)'	System	25 Aug 2020 16:11:15
	System	25 Aug 2020 16:11:15

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:14:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-25T12:11:01', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'bc33050a-309b-4379-b949-aa25b8c5fb06' User entered 'None (0)'	System	25 Aug 2020 16:11:15
	System	25 Aug 2020 16:11:15

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:14:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-25T12:11:03', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'bc33050a-309b-4379-b949-aa25b8c5fb06' User entered 'None (0)'	System	25 Aug 2020 16:11:15
	System	25 Aug 2020 16:11:15

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:14:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-25T12:11:05', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'bc33050a-309b-4379-b949-aa25b8c5fb06' User entered 'None (0)'	System	25 Aug 2020 16:11:15
	System	25 Aug 2020 16:11:15

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:14:43

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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-25T12:11:09', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'bc33050a-309b-4379-b949-aa25b8c5fb06' User entered 'No (N)'	System	25 Aug 2020 16:11:15
	System	25 Aug 2020 16:11:15

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:14:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-08-25T12:11:11', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'bc33050a-309b-4379-b949-aa25b8c5fb06' User entered '25 Aug 2020 12:11'	System	25 Aug 2020 16:11:15
	System	25 Aug 2020 16:11:15

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:14:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 20:11:22

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:14:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 20:11:22

US3372184

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:32:59
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	27 Aug 2020 20:01:12

US3372184

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:32:59
User entered '26 Aug 2020'	(b) (4) Alexandra Arango (b) (4)	27 Aug 2020 20:01:12

US3372184

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:32:59
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alexandra Arango (b) (4)	27 Aug 2020 20:01:12

US3372184

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:32:59
User entered empty.	(b) (4) Alexandra Arango (b) (4)	27 Aug 2020 20:01:12
	(b) (4)	

US3372184

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:33:34
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	27 Aug 2020 20:01:17

US3372184

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User entered 'I'	System	27 Aug 2020 20:01:17

US3372184

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:32:47
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	04 Sep 2020 20:03:51

US3372184

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 02:32:47
User entered '03 Sep 2020' reason for change: Data Entry Error	Mary Sergalis (b) (4)	10 Nov 2020 17:41:32
User entered '3 Sep 2020'	Alexandra Arango (b) (4) (b) (4)	04 Sep 2020 20:03:51

US3372184

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:32:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alexandra Arango (b) (4)	04 Sep 2020 20:03:51

US3372184

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:32:47
User entered empty.	(b) (4) Alexandra Arango (b) (4)	04 Sep 2020 20:03:51
	(b) (4)	

US3372184

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:33:34
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	04 Sep 2020 20:03:54

US3372184

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User entered 'I'	System	04 Sep 2020 20:03:54

US3372184

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:32:47
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	09 Sep 2020 18:20:56

US3372184

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4) (b) (4)	17 Feb 2021 02:32:47
User entered '09 Sep 2020' reason for change: Data Entry Error	Mary Sergalis (b) (4)	10 Nov 2020 17:41:49
User entered '9 Sep 2020'	Alexandra Arango (b) (4) (b) (4)	09 Sep 2020 18:20:56

US3372184

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:32:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alexandra Arango (b) (4)	09 Sep 2020 18:20:56

US3372184

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:32:47
User entered empty.	(b) (4) Alexandra Arango (b) (4) (b) (4)	09 Sep 2020 18:20:56

US3372184

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:33:34
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	09 Sep 2020 18:22:00

US3372184

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User entered 'I'	System	09 Sep 2020 18:22:00

US3372184

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:14:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:18:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:57:07

US3372184

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:18:42
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:57:07

US3372184

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:18:42
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 18:57:07

US3372184

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:14:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User entered 'VISIT2'	System	22 Sep 2020 18:57:07

US3372184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User accepted default value 'Pre-Dose (PREDOSE)'	Peter Jacob (b) (4) (b) (4)	24 Sep 2020 23:15:08

US3372184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:18:42
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	24 Sep 2020 23:15:08

US3372184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:18:42
User entered '22 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	24 Sep 2020 23:15:08

US3372184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:18:42
User entered '14:35'	(b) (4) Peter Jacob (b) (4) (b) (4)	24 Sep 2020 23:15:08

US3372184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User entered '22 Sep 2020 14:35'	System	24 Sep 2020 23:15:08

US3372184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:18:42
User entered '36.6' C	(b) (4) Peter Jacob (b) (4)	24 Sep 2020 23:15:08

US3372184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:18:42
User entered 'Oral (Oral)'	(b) (4) Peter Jacob (b) (4)	24 Sep 2020 23:15:08

US3372184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:18:42
User entered empty.	(b) (4) Peter Jacob (b) (4)	24 Sep 2020 23:15:08

US3372184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:18:42
User entered '54'	(b) (4) Peter Jacob (b) (4) (b) (4)	24 Sep 2020 23:15:08

US3372184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User entered 'bpm'	System	24 Sep 2020 23:15:08

US3372184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:18:42
User entered '16'	(b) (4) Peter Jacob (b) (4) (b) (4)	24 Sep 2020 23:15:08

US3372184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User entered 'breaths/min'	System	24 Sep 2020 23:15:08

US3372184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:18:42
User entered '160'	(b) (4) Peter Jacob (b) (4) (b) (4)	24 Sep 2020 23:15:08

US3372184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User entered 'mmHg'	System	24 Sep 2020 23:15:08

US3372184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:18:42
User entered '81'	(b) (4) Peter Jacob (b) (4)	24 Sep 2020 23:15:08

US3372184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User entered 'mmHg'	System	24 Sep 2020 23:15:08

US3372184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User accepted default value 'Post-Dose (POSTDOSE)'	Peter Jacob (b) (4) (b) (4)	24 Sep 2020 23:15:53

US3372184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:18:42
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	24 Sep 2020 23:15:53

US3372184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:18:42
User entered '22 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	24 Sep 2020 23:15:53

US3372184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:18:42
User entered '16:21'	(b) (4) Peter Jacob (b) (4) (b) (4)	24 Sep 2020 23:15:53

US3372184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User entered '22 Sep 2020 16:21'	System	24 Sep 2020 23:15:53

US3372184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:18:42
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 10:33:46
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs' (Site from System).	Peter Jacob (b) (4) (b) (4)	24 Sep 2020 23:16:01
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	24 Sep 2020 23:15:53
User entered '35.8' C	Peter Jacob (b) (4) (b) (4)	24 Sep 2020 23:15:53

US3372184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:18:42
User entered 'Oral (Oral)'	(b) (4) Peter Jacob (b) (4)	24 Sep 2020 23:15:53

US3372184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:18:42
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	24 Sep 2020 23:15:53

US3372184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:18:42
User entered '45'	(b) (4) Peter Jacob (b) (4) (b) (4)	24 Sep 2020 23:15:53

US3372184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User entered 'bpm'	System	24 Sep 2020 23:15:53

US3372184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:18:42
User entered '16'	(b) (4) Peter Jacob (b) (4) (b) (4)	24 Sep 2020 23:15:53

US3372184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User entered 'breaths/min'	System	24 Sep 2020 23:15:53

US3372184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:18:42
User entered '164'	(b) (4) Peter Jacob (b) (4)	24 Sep 2020 23:15:53

US3372184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User entered 'mmHg'	System	24 Sep 2020 23:15:53

US3372184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:18:42
User entered '79'	(b) (4) Peter Jacob (b) (4)	24 Sep 2020 23:15:53

US3372184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User entered 'mmHg'	System	24 Sep 2020 23:15:53

US3372184

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:14:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:18:42
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	24 Sep 2020 23:16:13

US3372184

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:14:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:18:42
User entered '22 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	24 Sep 2020 23:16:13

US3372184

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:14:43

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:18:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 19:50:15

US3372184

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:14:43

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:18:42
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 19:50:15

US3372184

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:18:42
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 19:50:15

US3372184

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:14:43

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User entered 'MRNA-1273 OR PLACEBO'	System	22 Sep 2020 19:50:15

US3372184

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:14:43

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:18:42
User entered '22 Sep 2020'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 19:50:15

US3372184

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:14:43

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:18:42
User entered '15:42'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 19:50:15

US3372184

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:14:43

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User entered '22 Sep 2020 15:42'	System	22 Sep 2020 19:50:15

US3372184

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:14:43

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:18:42
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 19:50:15

US3372184

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:14:43

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User entered 'ONCE'	System	22 Sep 2020 19:50:15

US3372184

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:14:43

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User entered 'INTRAMUSCULAR'	System	22 Sep 2020 19:50:15

US3372184

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:18:42
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	24 Sep 2020 23:16:21

US3372184

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:18:42
User entered '22 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	24 Sep 2020 23:16:21

US3372184

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:43

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 20:18:42
User entered '15:03'	(b) (4) Peter Jacob (b) (4) (b) (4)	24 Sep 2020 23:16:21

US3372184

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User entered '22 Sep 2020 15:03'	System	24 Sep 2020 23:16:21

US3372184

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:14:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:17:19
User entered '22 Sep 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	24 Sep 2020 23:16:34

US3372184

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:14:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Peter Jacob (b) (4) (b) (4)	24 Sep 2020 23:16:34

US3372184

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:14:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:17:19
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	24 Sep 2020 23:16:34

US3372184

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:14:43

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:17:19
User entered '14:59'	(b) (4) Peter Jacob (b) (4) (b) (4)	24 Sep 2020 23:16:34

US3372184

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:14:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User entered '22 Sep 2020 14:59'	System	24 Sep 2020 23:16:34

US3372184

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:14:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Peter Jacob (b) (4) (b) (4)	24 Sep 2020 23:16:34

US3372184

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:14:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:17:19
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	24 Sep 2020 23:16:34

US3372184

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:14:43

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:17:19
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	24 Sep 2020 23:16:34

US3372184

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:14:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User entered empty.	System	24 Sep 2020 23:16:34

US3372184

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:33:34
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4) (b) (4)	24 Sep 2020 23:16:39

US3372184

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User entered 'I'	System	24 Sep 2020 23:16:39

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	22 Sep 2020 19:50:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-22T16:21:53', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'b7f325ac-054b-444d-bb18-9edf8daabfa4' User entered 'Yes (Y)'	System	22 Sep 2020 20:22:09
	System	22 Sep 2020 20:22:09

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-22T16:21:58', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'b7f325ac-054b-444d-bb18-9edf8daabfa4' User entered '96.5'	System	22 Sep 2020 20:22:09
	System	22 Sep 2020 20:22:09

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-22T16:22:03', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'b7f325ac-054b-444d-bb18-9edf8daabfa4' User entered 'No (N)'	System	22 Sep 2020 20:22:09
	System	22 Sep 2020 20:22:09

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-22T16:22:07', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'b7f325ac-054b-444d-bb18-9edf8daabfa4' User entered '22 Sep 2020 16:22'	System	22 Sep 2020 20:22:09
	System	22 Sep 2020 20:22:09

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '22 Sep 2020 16:02'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '22 Sep 2020 18:32'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	22 Sep 2020 19:50:15
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-23T05:27:30', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '498331d2-7f77-4ae8-ab86-7c3ca240d3f0' User entered 'Yes (Y)'	System	23 Sep 2020 09:27:47
	System	23 Sep 2020 09:27:47

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-23T05:27:38', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '498331d2-7f77-4ae8-ab86-7c3ca240d3f0' User entered '98.0'	System	23 Sep 2020 09:27:47
	System	23 Sep 2020 09:27:47

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-23T05:27:42', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '498331d2-7f77-4ae8-ab86-7c3ca240d3f0' User entered 'No (N)'	System	23 Sep 2020 09:27:47
	System	23 Sep 2020 09:27:47

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-23T05:27:45', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '498331d2-7f77-4ae8-ab86-7c3ca240d3f0' User entered '23 Sep 2020 05:27'	System	23 Sep 2020 09:27:47
	System	23 Sep 2020 09:27:47

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '22 Sep 2020 19:27'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	22 Sep 2020 19:50:15
User entered 'Day 2'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:14:43

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-24T05:25:27', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '208237a1-fd31-4fd7-b7ca-9c2209093afd' User entered 'Yes (Y)'	System	24 Sep 2020 09:25:49
	System	24 Sep 2020 09:25:49

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:14:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-24T05:25:33', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '208237a1-fd31-4fd7-b7ca-9c2209093afd' User entered '97.8'	System	24 Sep 2020 09:25:49
	System	24 Sep 2020 09:25:49

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-24T05:25:36', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '208237a1-fd31-4fd7-b7ca-9c2209093afd' User entered 'No (N)'	System	24 Sep 2020 09:25:49
	System	24 Sep 2020 09:25:49

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:14:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-24T05:25:46', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '208237a1-fd31-4fd7-b7ca-9c2209093afd' User entered '24 Sep 2020 05:25'	System	24 Sep 2020 09:25:49
	System	24 Sep 2020 09:25:49

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:14:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:14:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	22 Sep 2020 19:50:15
User entered 'Day 3'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:14:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-25T08:24:06', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'dc91b2dd-9b22-4df2-8d5b-37d0d4077937'	System	25 Sep 2020 12:24:21
User entered 'Yes (Y)'	System	25 Sep 2020 12:24:21

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:14:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-25T08:24:11', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'dc91b2dd-9b22-4df2-8d5b-37d0d4077937' User entered '97.2'	System	25 Sep 2020 12:24:21
	System	25 Sep 2020 12:24:21

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-25T08:24:14', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'dc91b2dd-9b22-4df2-8d5b-37d0d4077937'	System	25 Sep 2020 12:24:21
User entered 'No (N)'	System	25 Sep 2020 12:24:21

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:14:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-25T08:24:18', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'dc91b2dd-9b22-4df2-8d5b-37d0d4077937' User entered '25 Sep 2020 08:24'	System	25 Sep 2020 12:24:21
	System	25 Sep 2020 12:24:21

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:14:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:14:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	22 Sep 2020 19:50:15
User entered 'Day 4'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:14:43

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-26T05:59:23', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'a2c3d19d-0ff6-49b9-8fca-b5f5f8d92788' User entered 'Yes (Y)'	System	26 Sep 2020 09:59:41
	System	26 Sep 2020 09:59:41

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:14:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-26T05:59:28', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'a2c3d19d-0ff6-49b9-8fca-b5f5f8d92788' User entered '97.2'	System	26 Sep 2020 09:59:41
	System	26 Sep 2020 09:59:41

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-26T05:59:34', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'a2c3d19d-0ff6-49b9-8fca-b5f5f8d92788'	System	26 Sep 2020 09:59:41
User entered 'No (N)'	System	26 Sep 2020 09:59:41

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:14:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-26T05:59:38', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'a2c3d19d-0ff6-49b9-8fca-b5f5f8d92788' User entered '26 Sep 2020 05:59'	System	26 Sep 2020 09:59:41
	System	26 Sep 2020 09:59:41

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:14:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:14:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	22 Sep 2020 19:50:15
User entered 'Day 5'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:14:43

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-27T06:38:51', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '29d6e8fe-9c13-4c99-a9db-feaa65a2f80f' User entered 'Yes (Y)'	System	27 Sep 2020 10:39:08
	System	27 Sep 2020 10:39:08

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:14:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-27T06:38:56', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '29d6e8fe-9c13-4c99-a9db-feaa65a2f80f' User entered '97.4'	System	27 Sep 2020 10:39:08
	System	27 Sep 2020 10:39:08

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-27T06:38:59', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '29d6e8fe-9c13-4c99-a9db-feaa65a2f80f' User entered 'No (N)'	System	27 Sep 2020 10:39:08
	System	27 Sep 2020 10:39:08

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:14:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-27T06:39:03', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '29d6e8fe-9c13-4c99-a9db-feaa65a2f80f' User entered '27 Sep 2020 06:39'	System	27 Sep 2020 10:39:08
	System	27 Sep 2020 10:39:08

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:14:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:14:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	22 Sep 2020 19:50:15
User entered 'Day 6'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:14:43

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-28T07:52:50', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '5e77623c-bd85-4e8d-904a-2138e5a98751' User entered 'Yes (Y)'	System	28 Sep 2020 11:53:07
	System	28 Sep 2020 11:53:07

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:14:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-28T07:52:54', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '5e77623c-bd85-4e8d-904a-2138e5a98751' User entered '97.6'	System	28 Sep 2020 11:53:07
	System	28 Sep 2020 11:53:07

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-28T07:53:01', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '5e77623c-bd85-4e8d-904a-2138e5a98751' User entered 'No (N)'	System	28 Sep 2020 11:53:07
	System	28 Sep 2020 11:53:07

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:14:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-28T07:53:04', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '5e77623c-bd85-4e8d-904a-2138e5a98751' User entered '28 Sep 2020 07:53'	System	28 Sep 2020 11:53:07
	System	28 Sep 2020 11:53:07

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:14:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:14:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	22 Sep 2020 19:50:15
User entered 'Day 7'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:14:43

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-29T11:21:29', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '7be67dbf-f047-488f-9eb8-65982b096150' User entered 'Yes (Y)'	System	29 Sep 2020 15:21:46
	System	29 Sep 2020 15:21:46

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:14:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-29T11:21:34', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '7be67dbf-f047-488f-9eb8-65982b096150' User entered '97.7'	System	29 Sep 2020 15:21:46
	System	29 Sep 2020 15:21:46

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-29T11:21:38', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '7be67dbf-f047-488f-9eb8-65982b096150'	System	29 Sep 2020 15:21:46
User entered 'No (N)'	System	29 Sep 2020 15:21:46

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:14:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-29T11:21:42', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '7be67dbf-f047-488f-9eb8-65982b096150' User entered '29 Sep 2020 11:21'	System	29 Sep 2020 15:21:46
	System	29 Sep 2020 15:21:46

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:14:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:14:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	22 Sep 2020 19:50:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-22T16:22:23', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'd526f414-9833-451b-ad90-0a283dd5df05'	System	22 Sep 2020 20:22:41
User entered 'None (1)'	System	22 Sep 2020 20:22:41

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-22T16:22:26', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'd526f414-9833-451b-ad90-0a283dd5df05' User entered 'No (N)'	System	22 Sep 2020 20:22:41
	System	22 Sep 2020 20:22:41

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-22T16:22:30', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'd526f414-9833-451b-ad90-0a283dd5df05' User entered 'No (N)'	System	22 Sep 2020 20:22:41
	System	22 Sep 2020 20:22:41

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-22T16:22:36', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'd526f414-9833-451b-ad90-0a283dd5df05'	System	22 Sep 2020 20:22:41
User entered 'None (1)'	System	22 Sep 2020 20:22:41

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-22T16:22:38', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'd526f414-9833-451b-ad90-0a283dd5df05' User entered '22 Sep 2020 16:22'	System	22 Sep 2020 20:22:41
	System	22 Sep 2020 20:22:41

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '22 Sep 2020 16:02'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '22 Sep 2020 18:32'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	22 Sep 2020 19:50:15
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-23T05:28:00', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '76a1dce4-745b-4663-8bf6-b2130e802e48' User entered 'None (1)'	System	23 Sep 2020 09:28:57
	System	23 Sep 2020 09:28:57

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-23T05:28:42', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '76a1dce4-745b-4663-8bf6-b2130e802e48' User entered 'No (N)'	System	23 Sep 2020 09:28:57
	System	23 Sep 2020 09:28:57

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-23T05:28:45', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '76a1dce4-745b-4663-8bf6-b2130e802e48' User entered 'No (N)'	System	23 Sep 2020 09:28:57
	System	23 Sep 2020 09:28:57

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-23T05:28:49', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '76a1dce4-745b-4663-8bf6-b2130e802e48' User entered 'None (1)'	System	23 Sep 2020 09:28:57
	System	23 Sep 2020 09:28:57

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-23T05:28:53', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '76a1dce4-745b-4663-8bf6-b2130e802e48' User entered '23 Sep 2020 05:28'	System	23 Sep 2020 09:28:57
	System	23 Sep 2020 09:28:57

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '22 Sep 2020 19:27'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	22 Sep 2020 19:50:15
User entered 'Day 2'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:14:43

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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-24T05:25:52', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'aa015b3f-b213-42bf-86df-e395bf77ba48'	System	24 Sep 2020 09:26:18
User entered 'None (1)'	System	24 Sep 2020 09:26:18

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:14:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-24T05:25:55', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'aa015b3f-b213-42bf-86df-e395bf77ba48' User entered 'No (N)'	System	24 Sep 2020 09:26:18
	System	24 Sep 2020 09:26:18

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-24T05:26:05', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'aa015b3f-b213-42bf-86df-e395bf77ba48'	System	24 Sep 2020 09:26:18
User entered 'No (N)'	System	24 Sep 2020 09:26:18

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:14:43

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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-24T05:26:09', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'aa015b3f-b213-42bf-86df-e395bf77ba48'	System	24 Sep 2020 09:26:18
User entered 'None (1)'	System	24 Sep 2020 09:26:18

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:14:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-24T05:26:12', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'aa015b3f-b213-42bf-86df-e395bf77ba48' User entered '24 Sep 2020 05:26'	System	24 Sep 2020 09:26:18
	System	24 Sep 2020 09:26:18

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:14:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:14:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	22 Sep 2020 19:50:15
User entered 'Day 3'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:14:43

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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-25T08:24:24', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'aedc8711-0644-4869-bbf7-1492d6392f12' User entered 'None (1)'	System	25 Sep 2020 12:24:41
	System	25 Sep 2020 12:24:41

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:14:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-25T08:24:28', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'aedc8711-0644-4869-bbf7-1492d6392f12' User entered 'No (N)'	System	25 Sep 2020 12:24:41
	System	25 Sep 2020 12:24:41

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-25T08:24:33', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'aedc8711-0644-4869-bbf7-1492d6392f12' User entered 'No (N)'	System	25 Sep 2020 12:24:41
	System	25 Sep 2020 12:24:41

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:14:43

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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-25T08:24:35', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'aedc8711-0644-4869-bbf7-1492d6392f12' User entered 'None (1)'	System	25 Sep 2020 12:24:41
	System	25 Sep 2020 12:24:41

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:14:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-25T08:24:38', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'aedc8711-0644-4869-bbf7-1492d6392f12' User entered '25 Sep 2020 08:24'	System	25 Sep 2020 12:24:41
	System	25 Sep 2020 12:24:41

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:14:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:14:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	22 Sep 2020 19:50:15
User entered 'Day 4'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:14:43

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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-26T05:59:43', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '47b092b9-7444-4c8c-a11c-6bd03b61540e' User entered 'None (1)'	System	26 Sep 2020 10:00:08
	System	26 Sep 2020 10:00:08

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:14:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-26T05:59:46', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '47b092b9-7444-4c8c-a11c-6bd03b61540e' User entered 'No (N)'	System	26 Sep 2020 10:00:08
	System	26 Sep 2020 10:00:08

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-26T05:59:55', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '47b092b9-7444-4c8c-a11c-6bd03b61540e' User entered 'No (N)'	System	26 Sep 2020 10:00:08
	System	26 Sep 2020 10:00:08

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:14:43

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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-26T05:59:59', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '47b092b9-7444-4c8c-a11c-6bd03b61540e' User entered 'None (1)'	System	26 Sep 2020 10:00:08
	System	26 Sep 2020 10:00:08

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:14:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-26T06:00:04', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '47b092b9-7444-4c8c-a11c-6bd03b61540e' User entered '26 Sep 2020 06:00'	System	26 Sep 2020 10:00:08
	System	26 Sep 2020 10:00:08

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:14:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:14:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	22 Sep 2020 19:50:15
User entered 'Day 5'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:14:43

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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-27T06:39:10', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'dae226d5-2fd1-4988-9e97-6ada1ea189f6'	System	27 Sep 2020 10:39:29
User entered 'None (1)'	System	27 Sep 2020 10:39:29

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:14:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-27T06:39:14', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'dae226d5-2fd1-4988-9e97-6ada1ea189f6' User entered 'No (N)'	System	27 Sep 2020 10:39:29
	System	27 Sep 2020 10:39:29

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-27T06:39:19', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'dae226d5-2fd1-4988-9e97-6ada1ea189f6' User entered 'No (N)'	System	27 Sep 2020 10:39:29
	System	27 Sep 2020 10:39:29

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:14:43

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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-27T06:39:21', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'dae226d5-2fd1-4988-9e97-6ada1ea189f6'	System	27 Sep 2020 10:39:29
User entered 'None (1)'	System	27 Sep 2020 10:39:29

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:14:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-27T06:39:24', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'dae226d5-2fd1-4988-9e97-6ada1ea189f6' User entered '27 Sep 2020 06:39'	System	27 Sep 2020 10:39:29
	System	27 Sep 2020 10:39:29

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:14:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:14:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	22 Sep 2020 19:50:15
User entered 'Day 6'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:14:43

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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-28T07:56:37', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'd7c93a20-8fe8-4836-9647-a3c68f1840a0' User entered 'None (1)'	System	28 Sep 2020 11:56:52
	System	28 Sep 2020 11:56:52

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:14:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-28T07:56:40', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'd7c93a20-8fe8-4836-9647-a3c68f1840a0' User entered 'No (N)'	System	28 Sep 2020 11:56:52
	System	28 Sep 2020 11:56:52

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-28T07:56:44', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'd7c93a20-8fe8-4836-9647-a3c68f1840a0' User entered 'No (N)'	System	28 Sep 2020 11:56:52
	System	28 Sep 2020 11:56:52

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:14:43

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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-28T07:56:48', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'd7c93a20-8fe8-4836-9647-a3c68f1840a0' User entered 'None (1)'	System	28 Sep 2020 11:56:52
	System	28 Sep 2020 11:56:52

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:14:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-28T07:56:50', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'd7c93a20-8fe8-4836-9647-a3c68f1840a0' User entered '28 Sep 2020 07:56'	System	28 Sep 2020 11:56:52
	System	28 Sep 2020 11:56:52

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:14:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:14:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	22 Sep 2020 19:50:15
User entered 'Day 7'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:14:43

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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-29T11:21:46', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '6f232467-8dd6-4644-bb97-7c95420699b4'	System	29 Sep 2020 15:22:02
User entered 'None (1)'	System	29 Sep 2020 15:22:02

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:14:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-29T11:21:50', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '6f232467-8dd6-4644-bb97-7c95420699b4'	System	29 Sep 2020 15:22:02
User entered 'No (N)'	System	29 Sep 2020 15:22:02

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-29T11:21:54', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '6f232467-8dd6-4644-bb97-7c95420699b4' User entered 'No (N)'	System	29 Sep 2020 15:22:02
	System	29 Sep 2020 15:22:02

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:14:43

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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-29T11:21:56', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '6f232467-8dd6-4644-bb97-7c95420699b4'	System	29 Sep 2020 15:22:02
User entered 'None (1)'	System	29 Sep 2020 15:22:02

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:14:43

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-29T11:22:00', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '6f232467-8dd6-4644-bb97-7c95420699b4' User entered '29 Sep 2020 11:22'	System	29 Sep 2020 15:22:02
	System	29 Sep 2020 15:22:02

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:14:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:14:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	22 Sep 2020 19:50:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-22T16:22:47', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '120a8c87-e2d5-4d90-80b2-1d94564ccae1' User entered 'None (0)'	System	22 Sep 2020 20:23:27
	System	22 Sep 2020 20:23:27

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-22T16:22:52', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '120a8c87-e2d5-4d90-80b2-1d94564ccae1' User entered 'None (0)'	System	22 Sep 2020 20:23:27
	System	22 Sep 2020 20:23:27

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-22T16:22:55', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '120a8c87-e2d5-4d90-80b2-1d94564ccae1' User entered 'None (0)'	System	22 Sep 2020 20:23:27
	System	22 Sep 2020 20:23:27

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-22T16:22:58', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '120a8c87-e2d5-4d90-80b2-1d94564ccae1' User entered 'None (0)'	System	22 Sep 2020 20:23:27
	System	22 Sep 2020 20:23:27

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-22T16:23:00', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '120a8c87-e2d5-4d90-80b2-1d94564ccae1' User entered 'None (0)'	System	22 Sep 2020 20:23:27
	System	22 Sep 2020 20:23:27

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-22T16:23:05', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '120a8c87-e2d5-4d90-80b2-1d94564ccae1' User entered 'None (0)'	System	22 Sep 2020 20:23:27
	System	22 Sep 2020 20:23:27

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-22T16:23:20', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '120a8c87-e2d5-4d90-80b2-1d94564ccae1' User entered 'No (N)'	System	22 Sep 2020 20:23:27
	System	22 Sep 2020 20:23:27

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-22T16:23:23', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '120a8c87-e2d5-4d90-80b2-1d94564ccae1' User entered '22 Sep 2020 16:23'	System	22 Sep 2020 20:23:27
	System	22 Sep 2020 20:23:27

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '22 Sep 2020 16:02'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:14:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '22 Sep 2020 18:32'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	22 Sep 2020 19:50:15
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-23T05:28:59', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'f80227ed-ccd4-496d-ad61-4f665f0298bc' User entered 'None (0)'	System	23 Sep 2020 09:29:25
	System	23 Sep 2020 09:29:25

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-23T05:29:04', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'f80227ed-ccd4-496d-ad61-4f665f0298bc' User entered 'None (0)'	System	23 Sep 2020 09:29:25
	System	23 Sep 2020 09:29:25

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-23T05:29:07', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'f80227ed-ccd4-496d-ad61-4f665f0298bc' User entered 'None (0)'	System	23 Sep 2020 09:29:25
	System	23 Sep 2020 09:29:25

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-23T05:29:10', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'f80227ed-ccd4-496d-ad61-4f665f0298bc' User entered 'None (0)'	System	23 Sep 2020 09:29:25
	System	23 Sep 2020 09:29:25

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-23T05:29:12', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'f80227ed-ccd4-496d-ad61-4f665f0298bc' User entered 'None (0)'	System	23 Sep 2020 09:29:25
	System	23 Sep 2020 09:29:25

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-23T05:29:15', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'f80227ed-ccd4-496d-ad61-4f665f0298bc' User entered 'None (0)'	System	23 Sep 2020 09:29:25
	System	23 Sep 2020 09:29:25

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-23T05:29:19', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'f80227ed-ccd4-496d-ad61-4f665f0298bc' User entered 'No (N)'	System	23 Sep 2020 09:29:25
	System	23 Sep 2020 09:29:25

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-23T05:29:22', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'f80227ed-ccd4-496d-ad61-4f665f0298bc' User entered '23 Sep 2020 05:29'	System	23 Sep 2020 09:29:25
	System	23 Sep 2020 09:29:25

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '22 Sep 2020 19:27'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:14:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	22 Sep 2020 19:50:15
User entered 'Day 2'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:14:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-24T05:26:17', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '0fe5f018-bd92-44cd-b358-d5273a82bff4' User entered 'None (0)'	System	24 Sep 2020 09:26:38
	System	24 Sep 2020 09:26:38

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:14:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-24T05:26:20', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '0fe5f018-bd92-44cd-b358-d5273a82bff4' User entered 'None (0)'	System	24 Sep 2020 09:26:38
	System	24 Sep 2020 09:26:38

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:14:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-24T05:26:22', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '0fe5f018-bd92-44cd-b358-d5273a82bff4' User entered 'None (0)'	System	24 Sep 2020 09:26:38
	System	24 Sep 2020 09:26:38

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:14:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-24T05:26:25', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '0fe5f018-bd92-44cd-b358-d5273a82bff4' User entered 'None (0)'	System	24 Sep 2020 09:26:38
	System	24 Sep 2020 09:26:38

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:14:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-24T05:26:28', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '0fe5f018-bd92-44cd-b358-d5273a82bff4' User entered 'None (0)'	System	24 Sep 2020 09:26:38
	System	24 Sep 2020 09:26:38

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:14:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-24T05:26:31', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '0fe5f018-bd92-44cd-b358-d5273a82bff4' User entered 'None (0)'	System	24 Sep 2020 09:26:38
	System	24 Sep 2020 09:26:38

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:14:43

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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-24T05:26:33', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '0fe5f018-bd92-44cd-b358-d5273a82bff4' User entered 'No (N)'	System	24 Sep 2020 09:26:38
	System	24 Sep 2020 09:26:38

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:14:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-24T05:26:36', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '0fe5f018-bd92-44cd-b358-d5273a82bff4' User entered '24 Sep 2020 05:26'	System	24 Sep 2020 09:26:38
	System	24 Sep 2020 09:26:38

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:14:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:14:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	22 Sep 2020 19:50:15
User entered 'Day 3'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:14:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-25T08:24:42', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '32d896c9-b05c-4ca9-97d5-19e2164eb382' User entered 'None (0)'	System	25 Sep 2020 12:25:07
	System	25 Sep 2020 12:25:07

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:14:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-25T08:24:44', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '32d896c9-b05c-4ca9-97d5-19e2164eb382' User entered 'None (0)'	System	25 Sep 2020 12:25:07
	System	25 Sep 2020 12:25:07

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:14:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-25T08:24:47', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '32d896c9-b05c-4ca9-97d5-19e2164eb382' User entered 'None (0)'	System	25 Sep 2020 12:25:07
	System	25 Sep 2020 12:25:07

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:14:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-25T08:24:49', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '32d896c9-b05c-4ca9-97d5-19e2164eb382' User entered 'None (0)'	System	25 Sep 2020 12:25:07
	System	25 Sep 2020 12:25:07

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:14:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-25T08:24:51', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '32d896c9-b05c-4ca9-97d5-19e2164eb382' User entered 'None (0)'	System	25 Sep 2020 12:25:07
	System	25 Sep 2020 12:25:07

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:14:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-25T08:24:53', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '32d896c9-b05c-4ca9-97d5-19e2164eb382' User entered 'None (0)'	System	25 Sep 2020 12:25:07
	System	25 Sep 2020 12:25:07

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:14:43

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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-25T08:24:56', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '32d896c9-b05c-4ca9-97d5-19e2164eb382' User entered 'No (N)'	System	25 Sep 2020 12:25:07
	System	25 Sep 2020 12:25:07

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:14:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-25T08:24:59', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '32d896c9-b05c-4ca9-97d5-19e2164eb382' User entered '25 Sep 2020 08:24'	System	25 Sep 2020 12:25:07
	System	25 Sep 2020 12:25:07

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:14:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:14:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	22 Sep 2020 19:50:15
User entered 'Day 4'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:14:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-26T06:00:10', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'c3c3b7e5-74a1-4815-a2ed-fae772c8f02c' User entered 'None (0)'	System	26 Sep 2020 10:00:37
	System	26 Sep 2020 10:00:37

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:14:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-26T06:00:14', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'c3c3b7e5-74a1-4815-a2ed-fae772c8f02c' User entered 'None (0)'	System	26 Sep 2020 10:00:37
	System	26 Sep 2020 10:00:37

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:14:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-26T06:00:17', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'c3c3b7e5-74a1-4815-a2ed-fae772c8f02c' User entered 'None (0)'	System	26 Sep 2020 10:00:37
	System	26 Sep 2020 10:00:37

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:14:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-26T06:00:20', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'c3c3b7e5-74a1-4815-a2ed-fae772c8f02c' User entered 'None (0)'	System	26 Sep 2020 10:00:37
	System	26 Sep 2020 10:00:37

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:14:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-26T06:00:22', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'c3c3b7e5-74a1-4815-a2ed-fae772c8f02c' User entered 'None (0)'	System	26 Sep 2020 10:00:37
	System	26 Sep 2020 10:00:37

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:14:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-26T06:00:25', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'c3c3b7e5-74a1-4815-a2ed-fae772c8f02c' User entered 'None (0)'	System	26 Sep 2020 10:00:37
	System	26 Sep 2020 10:00:37

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:14:43

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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-26T06:00:28', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'c3c3b7e5-74a1-4815-a2ed-fae772c8f02c' User entered 'Yes (Y)'	System	26 Sep 2020 10:00:37
	System	26 Sep 2020 10:00:37

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:14:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-26T06:00:32', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'c3c3b7e5-74a1-4815-a2ed-fae772c8f02c' User entered '26 Sep 2020 06:00'	System	26 Sep 2020 10:00:37
	System	26 Sep 2020 10:00:37

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:14:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:14:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	22 Sep 2020 19:50:15
User entered 'Day 5'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:14:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-27T06:39:28', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '3a58b96c-c69f-4b11-a14a-4086e01cdcd7' User entered 'None (0)'	System	27 Sep 2020 10:39:50
	System	27 Sep 2020 10:39:50

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:14:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-27T06:39:31', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '3a58b96c-c69f-4b11-a14a-4086e01cdcd7' User entered 'None (0)'	System	27 Sep 2020 10:39:50
	System	27 Sep 2020 10:39:50

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:14:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-27T06:39:33', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '3a58b96c-c69f-4b11-a14a-4086e01cdcd7' User entered 'None (0)'	System	27 Sep 2020 10:39:50
	System	27 Sep 2020 10:39:50

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:14:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-27T06:39:36', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '3a58b96c-c69f-4b11-a14a-4086e01cdcd7' User entered 'None (0)'	System	27 Sep 2020 10:39:50
	System	27 Sep 2020 10:39:50

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:14:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-27T06:39:38', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '3a58b96c-c69f-4b11-a14a-4086e01cdcd7' User entered 'None (0)'	System	27 Sep 2020 10:39:50
	System	27 Sep 2020 10:39:50

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:14:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-27T06:39:40', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '3a58b96c-c69f-4b11-a14a-4086e01cdcd7' User entered 'None (0)'	System	27 Sep 2020 10:39:50
	System	27 Sep 2020 10:39:50

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:14:43

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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-27T06:39:43', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '3a58b96c-c69f-4b11-a14a-4086e01cdcd7' User entered 'No (N)'	System	27 Sep 2020 10:39:50
	System	27 Sep 2020 10:39:50

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:14:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-27T06:39:47', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '3a58b96c-c69f-4b11-a14a-4086e01cdcd7' User entered '27 Sep 2020 06:39'	System	27 Sep 2020 10:39:50
	System	27 Sep 2020 10:39:50

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:14:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:14:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	22 Sep 2020 19:50:15
User entered 'Day 6'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:14:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-28T07:56:55', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'b66d72ba-e19a-4a02-95e0-b803157e2e7e' User entered 'None (0)'	System	28 Sep 2020 11:57:23
	System	28 Sep 2020 11:57:23

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:14:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-28T07:56:58', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'b66d72ba-e19a-4a02-95e0-b803157e2e7e' User entered 'None (0)'	System	28 Sep 2020 11:57:23
	System	28 Sep 2020 11:57:23

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:14:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-28T07:57:00', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'b66d72ba-e19a-4a02-95e0-b803157e2e7e' User entered 'None (0)'	System	28 Sep 2020 11:57:23
	System	28 Sep 2020 11:57:23

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:14:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-28T07:57:03', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'b66d72ba-e19a-4a02-95e0-b803157e2e7e' User entered 'None (0)'	System	28 Sep 2020 11:57:23
	System	28 Sep 2020 11:57:23

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:14:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-28T07:57:05', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'b66d72ba-e19a-4a02-95e0-b803157e2e7e' User entered 'None (0)'	System	28 Sep 2020 11:57:23
	System	28 Sep 2020 11:57:23

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:14:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-28T07:57:10', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'b66d72ba-e19a-4a02-95e0-b803157e2e7e' User entered 'None (0)'	System	28 Sep 2020 11:57:23
	System	28 Sep 2020 11:57:23

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:14:43

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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-28T07:57:14', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'b66d72ba-e19a-4a02-95e0-b803157e2e7e' User entered 'No (N)'	System	28 Sep 2020 11:57:23
	System	28 Sep 2020 11:57:23

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:14:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-28T07:57:19', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'b66d72ba-e19a-4a02-95e0-b803157e2e7e' User entered '28 Sep 2020 07:57'	System	28 Sep 2020 11:57:23
	System	28 Sep 2020 11:57:23

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:14:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:14:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	22 Sep 2020 19:50:15
User entered 'Day 7'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:14:43

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-29T11:22:06', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '1b811466-7879-4555-8cd1-0239e523fe76' User entered 'None (0)'	System	29 Sep 2020 15:22:40
	System	29 Sep 2020 15:22:40

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:14:43

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-29T11:22:09', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '1b811466-7879-4555-8cd1-0239e523fe76' User entered 'None (0)'	System	29 Sep 2020 15:22:40
	System	29 Sep 2020 15:22:40

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:14:43

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-29T11:22:12', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '1b811466-7879-4555-8cd1-0239e523fe76' User entered 'None (0)'	System	29 Sep 2020 15:22:40
	System	29 Sep 2020 15:22:40

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:14:43

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-29T11:22:14', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '1b811466-7879-4555-8cd1-0239e523fe76' User entered 'None (0)'	System	29 Sep 2020 15:22:40
	System	29 Sep 2020 15:22:40

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:14:43

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-29T11:22:17', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '1b811466-7879-4555-8cd1-0239e523fe76' User entered 'None (0)'	System	29 Sep 2020 15:22:40
	System	29 Sep 2020 15:22:40

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:14:43

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-29T11:22:19', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '1b811466-7879-4555-8cd1-0239e523fe76' User entered 'None (0)'	System	29 Sep 2020 15:22:40
	System	29 Sep 2020 15:22:40

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:14:43

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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-29T11:22:23', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '1b811466-7879-4555-8cd1-0239e523fe76' User entered 'No (N)'	System	29 Sep 2020 15:22:40
	System	29 Sep 2020 15:22:40

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:14:43

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-09-29T11:22:25', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '1b811466-7879-4555-8cd1-0239e523fe76' User entered '29 Sep 2020 11:22'	System	29 Sep 2020 15:22:40
	System	29 Sep 2020 15:22:40

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:14:43

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 19:50:15

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:14:43

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 19:50:15

US3372184

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:32:47
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	30 Sep 2020 16:50:06

US3372184

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:32:47
User closed query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:48:24
Query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.'	Mary Sergalis (b) (4)	10 Nov 2020 18:42:46
answered with 'Correct as entered. Safety call completed as per protocol schedule but subject is out of window due to an AE' (Site from System).		
User opened query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	30 Sep 2020 16:50:06
User entered '25 Sep 2020'	Danielle Theodore (b) (4) (b) (4)	30 Sep 2020 16:50:06

US3372184

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:32:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	30 Sep 2020 16:50:06

US3372184

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:32:47
User entered empty.	(b) (4) Danielle Theodore (b) (4)	30 Sep 2020 16:50:06
	(b) (4)	

US3372184

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:33:34
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	30 Sep 2020 16:50:30

US3372184

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User entered 'I'	System	30 Sep 2020 16:50:30

US3372184

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:32:47
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	30 Sep 2020 16:50:41

US3372184

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:32:47
User closed query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 14:19:22
Query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'visit 2 was pushed back due to lack of lab kits' (Site from System).	Danielle Theodore (b) (4) (b) (4)	06 Nov 2020 20:02:46
User opened query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	30 Sep 2020 16:50:41
User entered '30 Sep 2020'	Danielle Theodore (b) (4) (b) (4)	30 Sep 2020 16:50:41

US3372184

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:32:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4)	30 Sep 2020 16:50:41

US3372184

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:32:47
User entered empty.	(b) (4) Danielle Theodore (b) (4) (b) (4)	30 Sep 2020 16:50:41

US3372184

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:33:34
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	30 Sep 2020 16:51:12

US3372184

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User entered 'I'	System	30 Sep 2020 16:51:12

US3372184

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:32:59
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	07 Oct 2020 17:17:36

US3372184

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:32:59
User closed query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:42:50
Query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Date correct as entered.' (Site from System).	Mary Sergalis (b) (4)	10 Nov 2020 17:42:27
User opened query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	10 Nov 2020 17:42:05
User entered '07 Oct 2020' reason for change: Data Entry Error	Mary Sergalis (b) (4)	10 Nov 2020 17:42:05
User closed query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	08 Oct 2020 07:41:19
Query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Phone visit completed within window per protocol.' (Site from System).	Alexandra Arango (b) (4) (b) (4)	07 Oct 2020 17:17:43
User opened query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	07 Oct 2020 17:17:36
User entered '7 Oct 2020'	Alexandra Arango (b) (4) (b) (4)	07 Oct 2020 17:17:36

US3372184

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:32:59
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alexandra Arango (b) (4)	07 Oct 2020 17:17:36

US3372184

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:32:59
User entered empty.	(b) (4) Alexandra Arango (b) (4) (b) (4)	07 Oct 2020 17:17:36

US3372184

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:33:34
User entered 'Yes (Y)'	(b) (4) Alexandra Arango (b) (4)	07 Oct 2020 17:17:49

US3372184

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User entered 'I'	System	07 Oct 2020 17:17:49

US3372184

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:14:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:59:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:06:24

US3372184

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:14:43

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:59:32
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) (4), (b) (6)	16 Oct 2020 19:03:12
Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'per CRA window is based off of visit 1 date' (Site from System).	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:31:11
User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	14 Oct 2020 18:06:24
User entered '14 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 18:06:24

US3372184

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:59:32
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:06:24

US3372184

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:14:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User entered 'VISIT3'	System	14 Oct 2020 18:06:24

US3372184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:59:32
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:32:29

US3372184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:59:32
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:32:29

US3372184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:59:32
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:32:29

US3372184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User entered empty.	System	14 Oct 2020 18:32:29

US3372184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:59:32
User entered empty.	(b) (4) Peter Jacob (b) (4)	14 Oct 2020 18:32:29

US3372184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:59:32
User entered empty.	(b) (4) Peter Jacob (b) (4)	14 Oct 2020 18:32:29

US3372184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:59:32
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:32:29

US3372184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:59:32
User entered empty.	(b) (4) Peter Jacob (b) (4)	14 Oct 2020 18:32:29

US3372184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User entered empty.	System	14 Oct 2020 18:32:29

US3372184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:59:32
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:32:29

US3372184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User entered empty.	System	14 Oct 2020 18:32:29

US3372184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:59:32
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:32:29

US3372184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User entered empty.	System	14 Oct 2020 18:32:29

US3372184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:59:32
User entered empty.	(b) (4) Peter Jacob (b) (4)	14 Oct 2020 18:32:29

US3372184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User entered empty.	System	14 Oct 2020 18:32:29

US3372184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24

US3372184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24

US3372184

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:14:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:59:32
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	14 Oct 2020 18:32:51

US3372184

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:14:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:59:32
User entered empty.	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:32:51

US3372184

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:59:32
User entered 'Yes (Y)'	(b) (4) Peter Jacob (b) (4)	14 Oct 2020 18:33:59

US3372184

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:59:32
User entered '14 Oct 2020'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:33:59

US3372184

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:43

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 19:59:32
User entered '14:14'	(b) (4) Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:33:59

US3372184

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User entered '14 Oct 2020 14:14'	System	14 Oct 2020 18:33:59

US3372184

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:33:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:06:32

US3372184

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User entered 'I'	System	14 Oct 2020 18:06:32

US3372184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	19 Aug 2020 20:11:22
User entered 'Day 64'	System	19 Aug 2020 20:11:22

US3372184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-10-19T08:43:44', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '46ce3f2d-ee93-4409-a9ae-3461fbddba56'	System	19 Oct 2020 12:43:57
User entered 'No (N)'	System	19 Oct 2020 12:43:57

US3372184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Have you been exposed to someone with 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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-10-19T08:43:49', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '46ce3f2d-ee93-4409-a9ae-3461fbddba56'	System	19 Oct 2020 12:43:57
User entered 'No (N)'	System	19 Oct 2020 12:43:57

US3372184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-10-19T08:43:55', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '46ce3f2d-ee93-4409-a9ae-3461fbddba56' User entered '19 Oct 2020 08:43:55'	System	19 Oct 2020 12:43:57
	System	19 Oct 2020 12:43:57

US3372184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	19 Aug 2020 20:11:22
User entered '19 Oct 2020 00:01'	System	19 Aug 2020 20:11:22

US3372184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	19 Aug 2020 20:11:22
User entered '23 Oct 2020 23:59'	System	19 Aug 2020 20:11:22

US3372184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	19 Aug 2020 20:11:22
User entered 'Day 71'	System	19 Aug 2020 20:11:22

US3372184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-10-26T06:04:18', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '848b08f9-e604-4b41-95a4-3b3cdfbdf8b4'	System	26 Oct 2020 10:04:32
User entered 'No (N)'	System	26 Oct 2020 10:04:32

US3372184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

Have you been exposed to someone with 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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-10-26T06:04:22', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '848b08f9-e604-4b41-95a4-3b3cdfbdf8b4'	System	26 Oct 2020 10:04:32
User entered 'No (N)'	System	26 Oct 2020 10:04:32

US3372184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-10-26T06:04:26', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '848b08f9-e604-4b41-95a4-3b3cdfbdf8b4' User entered '26 Oct 2020 06:04:26'	System	26 Oct 2020 10:04:32
	System	26 Oct 2020 10:04:32

US3372184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	19 Aug 2020 20:11:22
User entered '26 Oct 2020 00:01'	System	19 Aug 2020 20:11:22

US3372184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	19 Aug 2020 20:11:22
User entered '30 Oct 2020 23:59'	System	19 Aug 2020 20:11:22

US3372184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	19 Aug 2020 20:11:22
User entered 'Day 78'	System	19 Aug 2020 20:11:22

US3372184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-11-02T09:03:55', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '544bd50a-b9b2-446f-aefa-e5dfb086d5ca' User entered 'No (N)'	System	02 Nov 2020 14:04:07
	System	02 Nov 2020 14:04:07

US3372184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

Have you been exposed to someone with 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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-11-02T09:04:01', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '544bd50a-b9b2-446f-aefa-e5dfb086d5ca' User entered 'No (N)'	System	02 Nov 2020 14:04:07
	System	02 Nov 2020 14:04:07

US3372184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-11-02T09:04:05', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '544bd50a-b9b2-446f-aefa-e5dfb086d5ca' User entered '02 Nov 2020 09:04:05'	System	02 Nov 2020 14:04:07
	System	02 Nov 2020 14:04:07

US3372184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	19 Aug 2020 20:11:22
User entered '02 Nov 2020 00:01'	System	19 Aug 2020 20:11:22

US3372184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	19 Aug 2020 20:11:22
User entered '06 Nov 2020 23:59'	System	19 Aug 2020 20:11:22

US3372184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	19 Aug 2020 20:11:22
User entered 'Day 92'	System	19 Aug 2020 20:11:22

US3372184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2020-11-18T13:02:01', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '223e1578-4744-4d64-8c85-2489753c5691'	System	18 Nov 2020 18:02:15
User entered 'No (N)'	System	18 Nov 2020 18:02:15

US3372184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Have you been exposed to someone with 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 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2020-11-18T13:02:08', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '223e1578-4744-4d64-8c85-2489753c5691'	System	18 Nov 2020 18:02:15
User entered 'No (N)'	System	18 Nov 2020 18:02:15

US3372184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2020-11-18T13:02:12', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '223e1578-4744-4d64-8c85-2489753c5691' User entered '18 Nov 2020 13:02:12'	System	18 Nov 2020 18:02:15
	System	18 Nov 2020 18:02:15

US3372184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	19 Aug 2020 20:11:22
User entered '16 Nov 2020 00:01'	System	19 Aug 2020 20:11:22

US3372184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 06:51:42
Data entry locked.	System	19 Aug 2020 20:11:22
User entered '20 Nov 2020 23:59'	System	19 Aug 2020 20:11:22

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2020-11-23T03:38:19', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'c42e1d31-21bb-4df6-9b0c-88da4039f21b' User entered 'No (N)'	System	23 Nov 2020 08:38:37

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Have you been exposed to someone with 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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2020-11-23T03:38:25', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'c42e1d31-21bb-4df6-9b0c-88da4039f21b' User entered 'No (N)'	System	23 Nov 2020 08:38:37

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2020-11-23T03:38:32', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'c42e1d31-21bb-4df6-9b0c-88da4039f21b' User entered '23 Nov 2020 03:38:32'	System	23 Nov 2020 08:38:37
	System	23 Nov 2020 08:38:37

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2020-11-27T03:41:21', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '67278d45-7481-442b-ac8e-c6981043d882'	System	27 Nov 2020 08:41:59
User entered 'No (N)'	System	27 Nov 2020 08:41:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Have you been exposed to someone with 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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2020-11-27T03:41:42', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '67278d45-7481-442b-ac8e-c6981043d882'	System	27 Nov 2020 08:41:59
User entered 'No (N)'	System	27 Nov 2020 08:41:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2020-11-27T03:41:55', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '67278d45-7481-442b-ac8e-c6981043d882'	System	27 Nov 2020 08:41:59
User entered '27 Nov 2020 03:41:55'	System	27 Nov 2020 08:41:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2020-12-04T00:01:42', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'c50cb8bd-8e10-4149-aad5-fad2e829c2ed' User entered 'No (N)'	System	04 Dec 2020 05:02:13
	System	04 Dec 2020 05:02:13

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

Have you been exposed to someone with 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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2020-12-04T00:01:47', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'c50cb8bd-8e10-4149-aad5-fad2e829c2ed' User entered 'No (N)'	System	04 Dec 2020 05:02:13

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2020-12-04T00:01:55', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'c50cb8bd-8e10-4149-aad5-fad2e829c2ed' User entered '04 Dec 2020 00:01:55'	System	04 Dec 2020 05:02:13
	System	04 Dec 2020 05:02:13

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2020-12-11T05:30:30', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '5d7d5084-ad9f-4f2c-9ffc-d81b58ddb59a'	System	11 Dec 2020 10:30:47
User entered 'No (N)'	System	11 Dec 2020 10:30:47

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

Have you been exposed to someone with 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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2020-12-11T05:30:39', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '5d7d5084-ad9f-4f2c-9ffc-d81b58ddb59a'	System	11 Dec 2020 10:30:47
User entered 'No (N)'	System	11 Dec 2020 10:30:47

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2020-12-11T05:30:42', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '5d7d5084-ad9f-4f2c-9ffc-d81b58ddb59a' User entered '11 Dec 2020 05:30:42'	System	11 Dec 2020 10:30:47
	System	11 Dec 2020 10:30:47

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2020-12-20T18:58:41', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'ff732a5e-f027-4305-9b4a-7114452e9215'	System	20 Dec 2020 23:58:52
User entered 'No (N)'	System	20 Dec 2020 23:58:52

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

Have you been exposed to someone with 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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2020-12-20T18:58:45', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'ff732a5e-f027-4305-9b4a-7114452e9215'	System	20 Dec 2020 23:58:52
User entered 'No (N)'	System	20 Dec 2020 23:58:52

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2020-12-20T18:58:49', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'ff732a5e-f027-4305-9b4a-7114452e9215'	System	20 Dec 2020 23:58:52
User entered '20 Dec 2020 18:58:49'	System	20 Dec 2020 23:58:52

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2020-12-25T02:31:52', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'dc84d268-1243-486c-8a6b-dc08a5ac9c9f'	System	25 Dec 2020 07:32:34
User entered 'No (N)'	System	25 Dec 2020 07:32:34

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

Have you been exposed to someone with 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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2020-12-25T02:32:03', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'dc84d268-1243-486c-8a6b-dc08a5ac9c9f'	System	25 Dec 2020 07:32:34
User entered 'No (N)'	System	25 Dec 2020 07:32:34

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2020-12-25T02:32:32', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'dc84d268-1243-486c-8a6b-dc08a5ac9c9f' User entered '25 Dec 2020 02:32:32'	System	25 Dec 2020 07:32:34
	System	25 Dec 2020 07:32:34

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-01-01T02:05:55', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'beed99a6-1a44-4825-a3a4-d72517376f66'	System	01 Jan 2021 07:06:31
User entered 'No (N)'	System	01 Jan 2021 07:06:31

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

Have you been exposed to someone with 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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-01-01T02:06:15', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'beed99a6-1a44-4825-a3a4-d72517376f66'	System	01 Jan 2021 07:06:31
User entered 'No (N)'	System	01 Jan 2021 07:06:31

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-01-01T02:06:29', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'beed99a6-1a44-4825-a3a4-d72517376f66' User entered '01 Jan 2021 02:06:29'	System	01 Jan 2021 07:06:31
	System	01 Jan 2021 07:06:31

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-01-10T12:00:34', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'a421bfab-2cca-4e76-8a39-e858256f8601' User entered 'No (N)'	System	10 Jan 2021 17:01:08
	System	10 Jan 2021 17:01:08

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

Have you been exposed to someone with 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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-01-10T12:00:40', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'a421bfab-2cca-4e76-8a39-e858256f8601'	System	10 Jan 2021 17:01:08
User entered 'No (N)'	System	10 Jan 2021 17:01:08

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-01-10T12:00:46', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'a421bfab-2cca-4e76-8a39-e858256f8601' User entered '10 Jan 2021 12:00:46'	System	10 Jan 2021 17:01:08
	System	10 Jan 2021 17:01:08

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-01-15T02:45:53', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'a12933df-090b-4ecb-9c60-d52b9a0fea5d'	System	15 Jan 2021 07:47:30
User entered 'Yes (Y)'	System	15 Jan 2021 07:47:30

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

Have you been exposed to someone with 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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-01-15T02:46:02', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'a12933df-090b-4ecb-9c60-d52b9a0fea5d'	System	15 Jan 2021 07:47:30
User entered 'No (N)'	System	15 Jan 2021 07:47:30

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-01-15T02:46:20', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'a12933df-090b-4ecb-9c60-d52b9a0fea5d' User entered 'No (N)'	System	15 Jan 2021 07:47:30

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-01-15T02:46:56', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'a12933df-090b-4ecb-9c60-d52b9a0fea5d'	System	15 Jan 2021 07:47:30
User entered 'No (N)'	System	15 Jan 2021 07:47:30

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-01-15T02:47:25', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'a12933df-090b-4ecb-9c60-d52b9a0fea5d' User entered '15 Jan 2021 02:47:25'	System	15 Jan 2021 07:47:30
	System	15 Jan 2021 07:47:30

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-01-22T04:47:50', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '78eac63a-223f-4e6d-80fe-57ee88192a2f' User entered 'Yes (Y)'	System	22 Jan 2021 09:49:00
	System	22 Jan 2021 09:49:00

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

Have you been exposed to someone with 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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-01-22T04:48:08', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '78eac63a-223f-4e6d-80fe-57ee88192a2f' User entered 'No (N)'	System	22 Jan 2021 09:49:00

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-01-22T04:48:18', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '78eac63a-223f-4e6d-80fe-57ee88192a2f' User entered 'No (N)'	System	22 Jan 2021 09:49:00

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-01-22T04:48:35', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '78eac63a-223f-4e6d-80fe-57ee88192a2f' User entered 'No (N)'	System	22 Jan 2021 09:49:00

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-01-22T04:48:58', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '78eac63a-223f-4e6d-80fe-57ee88192a2f' User entered '22 Jan 2021 04:48:58'	System	22 Jan 2021 09:49:00

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-01-29T04:43:59', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'dfa08aa6-8c1b-4a4e-b1f2-45bcd610eb1d'	System	29 Jan 2021 09:44:14
User entered 'No (N)'	System	29 Jan 2021 09:44:14

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Have you been exposed to someone with 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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-01-29T04:44:07', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'dfa08aa6-8c1b-4a4e-b1f2-45bcd610eb1d'	System	29 Jan 2021 09:44:14
User entered 'No (N)'	System	29 Jan 2021 09:44:14

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-01-29T04:44:13', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'dfa08aa6-8c1b-4a4e-b1f2-45bcd610eb1d' User entered '29 Jan 2021 04:44:13'	System	29 Jan 2021 09:44:14
	System	29 Jan 2021 09:44:14

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-02-05T04:00:53', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '18318cc4-81c8-4617-a2f9-39ff2801bc78'	System	05 Feb 2021 09:01:17
User entered 'No (N)'	System	05 Feb 2021 09:01:17

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

Have you been exposed to someone with 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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-02-05T04:01:02', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '18318cc4-81c8-4617-a2f9-39ff2801bc78'	System	05 Feb 2021 09:01:17
User entered 'No (N)'	System	05 Feb 2021 09:01:17

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-02-05T04:01:13', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '18318cc4-81c8-4617-a2f9-39ff2801bc78'	System	05 Feb 2021 09:01:17
User entered '05 Feb 2021 04:01:13'	System	05 Feb 2021 09:01:17

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-02-12T04:19:35', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '4c273889-342d-4aec-b9ca-f783a9ecd786'	System	12 Feb 2021 09:19:59
User entered 'No (N)'	System	12 Feb 2021 09:19:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Have you been exposed to someone with 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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-02-12T04:19:48', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '4c273889-342d-4aec-b9ca-f783a9ecd786'	System	12 Feb 2021 09:19:59
User entered 'No (N)'	System	12 Feb 2021 09:19:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-02-12T04:19:57', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '4c273889-342d-4aec-b9ca-f783a9ecd786'	System	12 Feb 2021 09:19:59
User entered '12 Feb 2021 04:19:57'	System	12 Feb 2021 09:19:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-02-19T02:01:27', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'f57dab90-94e4-4309-91f7-e1d500488acf' User entered 'No (N)'	System	19 Feb 2021 07:01:46
	System	19 Feb 2021 07:01:46

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

Have you been exposed to someone with 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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-02-19T02:01:37', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'f57dab90-94e4-4309-91f7-e1d500488acf' User entered 'No (N)'	System	19 Feb 2021 07:01:46
	System	19 Feb 2021 07:01:46

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-02-19T02:01:42', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'f57dab90-94e4-4309-91f7-e1d500488acf' User entered '19 Feb 2021 02:01:42'	System	19 Feb 2021 07:01:46
	System	19 Feb 2021 07:01:46

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-02-26T03:44:10-05:00', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'f9956ae0-cca2-458c-ba18-e9d594c0a229'	System	26 Feb 2021 08:44:20
User entered 'No (N)'	System	26 Feb 2021 08:44:20

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

Have you been exposed to someone with 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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-02-26T03:43:36-05:00', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'f9956ae0-cca2-458c-ba18-e9d594c0a229'	System	26 Feb 2021 08:44:20
User entered 'No (N)'	System	26 Feb 2021 08:44:20

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-02-26T03:44:18-05:00', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'f9956ae0-cca2-458c-ba18-e9d594c0a229' User entered '26 Feb 2021 08:44:18'	System	26 Feb 2021 08:44:20
	System	26 Feb 2021 08:44:20

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-03-05T00:09:21-05:00', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'd1dec619-d815-4de8-9d96-b4830d696389'	System	05 Mar 2021 05:09:52
User entered 'No (N)'	System	05 Mar 2021 05:09:52

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

Have you been exposed to someone with 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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-03-05T00:09:30-05:00', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'd1dec619-d815-4de8-9d96-b4830d696389'	System	05 Mar 2021 05:09:52
User entered 'No (N)'	System	05 Mar 2021 05:09:52

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-03-05T00:09:34-05:00', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'd1dec619-d815-4de8-9d96-b4830d696389'	System	05 Mar 2021 05:09:52
User entered '05 Mar 2021 00:09:34'	System	05 Mar 2021 05:09:52

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-03-12T00:02:46-05:00', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '35aacdab-5ca7-4fe9-ad9a-0ea5348d20a3'	System	12 Mar 2021 05:04:18
User entered 'No (N)'	System	12 Mar 2021 05:04:18

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

Have you been exposed to someone with 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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-03-12T00:02:50-05:00', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '35aacdab-5ca7-4fe9-ad9a-0ea5348d20a3'	System	12 Mar 2021 05:04:18
User entered 'No (N)'	System	12 Mar 2021 05:04:18

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-03-12T00:03:06-05:00', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '35aacdab-5ca7-4fe9-ad9a-0ea5348d20a3'	System	12 Mar 2021 05:04:18
User entered '12 Mar 2021 00:03:06'	System	12 Mar 2021 05:04:18

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-03-19T01:17:35-04:00', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '295d422b-ed71-4e7d-be73-bbd45d429a18'	System	19 Mar 2021 05:19:30
User entered 'Yes (Y)'	System	19 Mar 2021 05:19:30

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

Have you been exposed to someone with 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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-03-19T01:17:43-04:00', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '295d422b-ed71-4e7d-be73-bbd45d429a18'	System	19 Mar 2021 05:19:30
User entered 'No (N)'	System	19 Mar 2021 05:19:30

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-03-19T01:17:51-04:00', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '295d422b-ed71-4e7d-be73-bbd45d429a18'	System	19 Mar 2021 05:19:30
User entered 'No (N)'	System	19 Mar 2021 05:19:30

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-03-19T01:18:33-04:00', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '295d422b-ed71-4e7d-be73-bbd45d429a18'	System	19 Mar 2021 05:19:30
User entered 'Yes (Y)'	System	19 Mar 2021 05:19:30

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Please 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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-03-19T01:18:43-04:00', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '295d422b-ed71-4e7d-be73-bbd45d429a18'	System	19 Mar 2021 05:19:30
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Mar 2021 05:19:30

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-03-19T01:19:16-04:00', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '295d422b-ed71-4e7d-be73-bbd45d429a18'	System	19 Mar 2021 05:19:30
User entered '19 Mar 2021 01:19:16'	System	19 Mar 2021 05:19:30

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-03-26T01:06:29-04:00', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '5f934c54-53c2-4e18-942d-9ba5e8988db4'	System	26 Mar 2021 05:06:58
User entered 'No (N)'	System	26 Mar 2021 05:06:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

Have you been exposed to someone with 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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-03-26T01:06:39-04:00', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '5f934c54-53c2-4e18-942d-9ba5e8988db4'	System	26 Mar 2021 05:06:58
User entered 'No (N)'	System	26 Mar 2021 05:06:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-03-26T01:06:44-04:00', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '5f934c54-53c2-4e18-942d-9ba5e8988db4' User entered '26 Mar 2021 01:06:44'	System	26 Mar 2021 05:06:58
	System	26 Mar 2021 05:06:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-04-02T02:31:14-04:00', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'ebf88838-2557-49c0-a204-9d2844360c01'	System	02 Apr 2021 06:31:30
User entered 'No (N)'	System	02 Apr 2021 06:31:30

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

Have you been exposed to someone with 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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-04-02T02:31:23-04:00', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'ebf88838-2557-49c0-a204-9d2844360c01'	System	02 Apr 2021 06:31:30
User entered 'No (N)'	System	02 Apr 2021 06:31:30

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-04-02T02:31:27-04:00', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'ebf88838-2557-49c0-a204-9d2844360c01'	System	02 Apr 2021 06:31:30
User entered '02 Apr 2021 02:31:27'	System	02 Apr 2021 06:31:30

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-04-09T00:05:17-04:00', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '35c071f4-8477-4361-8db4-290cd549bd96'	System	09 Apr 2021 04:06:34
User entered 'No (N)'	System	09 Apr 2021 04:06:34

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

Have you been exposed to someone with 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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-04-09T00:05:23-04:00', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '35c071f4-8477-4361-8db4-290cd549bd96'	System	09 Apr 2021 04:06:34
User entered 'No (N)'	System	09 Apr 2021 04:06:34

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-04-09T00:05:27-04:00', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '35c071f4-8477-4361-8db4-290cd549bd96'	System	09 Apr 2021 04:06:34
User entered '09 Apr 2021 00:05:27'	System	09 Apr 2021 04:06:34

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-04-16T03:30:13-04:00', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'eb5a927d-f19a-4a1b-90e0-55e15255f887'	System	23 Apr 2021 07:42:38
User entered 'No (N)'	System	23 Apr 2021 07:42:38

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

Have you been exposed to someone with 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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-04-16T03:30:20-04:00', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'eb5a927d-f19a-4a1b-90e0-55e15255f887'	System	23 Apr 2021 07:42:38
User entered 'No (N)'	System	23 Apr 2021 07:42:38

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-04-16T03:30:26-04:00', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'eb5a927d-f19a-4a1b-90e0-55e15255f887'	System	23 Apr 2021 07:42:38
User entered '16 Apr 2021 03:30:26'	System	23 Apr 2021 07:42:38

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-04-23T03:42:38-04:00', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'aee763a1-30b7-42da-a9fb-b44bb84cd83a' User entered 'No (N)'	System	23 Apr 2021 07:43:02
	System	23 Apr 2021 07:43:02

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

Have you been exposed to someone with 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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-04-23T03:42:44-04:00', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'aee763a1-30b7-42da-a9fb-b44bb84cd83a' User entered 'No (N)'	System	23 Apr 2021 07:43:02

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-04-23T03:42:48-04:00', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'aee763a1-30b7-42da-a9fb-b44bb84cd83a' User entered '23 Apr 2021 03:42:48'	System	23 Apr 2021 07:43:02
	System	23 Apr 2021 07:43:02

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-04-30T05:47:12-04:00', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'f0c1363b-0338-48c3-84b0-3fb1fa294517'	System	30 Apr 2021 09:47:27
User entered 'No (N)'	System	30 Apr 2021 09:47:27

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

Have you been exposed to someone with 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 (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-04-30T05:47:19-04:00', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'f0c1363b-0338-48c3-84b0-3fb1fa294517'	System	30 Apr 2021 09:47:27
User entered 'No (N)'	System	30 Apr 2021 09:47:27

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-04-30T05:47:23-04:00', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: 'f0c1363b-0338-48c3-84b0-3fb1fa294517'	System	30 Apr 2021 09:47:27
User entered '30 Apr 2021 05:47:23'	System	30 Apr 2021 09:47:27

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '21 Oct 2022 00:01'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:14:43

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered '25 Oct 2022 23:59'	System	19 Nov 2020 23:10:58

US3372184

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:14:43

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)	26 Apr 2021 06:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-03-05T00:08:59-05:00', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '70f912d3-db1f-4dbf-acc7-8c7a0da15208'	System	05 Mar 2021 05:09:11
User entered 'No (N)'	System	05 Mar 2021 05:09:11

US3372184

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:14:43

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:49:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2B2FF861-407A-4C9E-8C24-4028448327E2)', Time: '2021-03-05T00:09:05-05:00', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '70f912d3-db1f-4dbf-acc7-8c7a0da15208'	System	05 Mar 2021 05:09:11
User entered '05 Mar 2021 00:09:05'	System	05 Mar 2021 05:09:11

US3372184

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:32:59
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	17 Nov 2020 18:08:05

US3372184

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:32:59
User entered '17 Nov 2020'	(b) (4) Danielle Theodore (b) (4)	17 Nov 2020 18:08:05
	(b) (4)	

US3372184

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:32:59
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4)	17 Nov 2020 18:08:05
	(b) (4)	

US3372184

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:32:59
User entered empty.	(b) (4) Danielle Theodore (b) (4) (b) (4)	17 Nov 2020 18:08:05

US3372184

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:33:34
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	17 Nov 2020 18:08:29
	(b) (4)	

US3372184

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 07:14:24
User entered 'I'	System	17 Nov 2020 18:08:29

US3372184

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:04:58
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:32:47
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	21 Dec 2020 21:43:51

US3372184

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:04:58
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:32:47
User entered '21 Dec 2020'	(b) (4) Danielle Theodore (b) (4)	21 Dec 2020 21:43:51
	(b) (4)	

US3372184

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:04:58
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:32:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4)	21 Dec 2020 21:43:51

US3372184

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:04:58
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:32:47
User entered empty.	(b) (4) Danielle Theodore (b) (4) (b) (4)	21 Dec 2020 21:43:51

US3372184

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:04:58
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:33:34
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	21 Dec 2020 21:44:09

US3372184

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:04:58
User entered 'I'	System	21 Dec 2020 21:44:09

US3372184

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:04:58
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:32:47
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	20 Jan 2021 19:50:19

US3372184

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:04:58
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:32:47
User entered '20 Jan 2021'	(b) (4) Danielle Theodore (b) (4) (b) (4)	20 Jan 2021 19:50:19

US3372184

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:04:58
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:32:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	20 Jan 2021 19:50:19

US3372184

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:04:58
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:32:47
User entered empty.	(b) (4) Danielle Theodore (b) (4)	20 Jan 2021 19:50:19
	(b) (4)	

US3372184

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:04:58
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:33:34
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	20 Jan 2021 19:50:27

US3372184

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:04:58
User entered 'I'	System	20 Jan 2021 19:50:27

US3372184

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:04:58
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:32:47
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	13 Feb 2021 01:03:26

US3372184

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:04:58
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:32:47
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 14:39:52
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'date correct as entered' (Site from System).	Danielle Theodore (b) (4) (b) (4)	13 Feb 2021 01:03:43
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	13 Feb 2021 01:03:26
User entered '12 Feb 2021'	Danielle Theodore (b) (4) (b) (4)	13 Feb 2021 01:03:26

US3372184

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:04:58
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:32:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	13 Feb 2021 01:03:26

US3372184

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:04:58
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:32:47
User entered empty.	(b) (4) Danielle Theodore (b) (4) (b) (4)	13 Feb 2021 01:03:26

US3372184

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:04:58
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:33:34
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	13 Feb 2021 01:04:07

US3372184

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:04:58
User entered 'I'	System	13 Feb 2021 01:04:07

US3372184

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:14:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:04:58
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:21:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:12:41

US3372184

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:04:58
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:21:44
User entered '15 Mar 2021'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:12:41

US3372184

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:04:58
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:21:44
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:12:41

US3372184

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:14:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:04:58
User entered 'VISIT4'	System	16 Mar 2021 15:12:41

US3372184

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:04:58
User signature succeeded.	Mira Baron (b) (4)	31 Mar 2021 14:26:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:09:20

US3372184

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:04:58
User signature succeeded.	Mira Baron (b) (4)	31 Mar 2021 14:26:03
User entered '15 Mar 2021'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:09:20

US3372184

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:04:58
User signature succeeded.	Mira Baron (b) (4)	31 Mar 2021 14:26:03
User entered '13:52'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:09:20

US3372184

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:04:58
User entered '15 Mar 2021 13:52'	System	30 Mar 2021 20:09:20

US3372184

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:04:58
User signature succeeded.	Mira Baron (b) (4)	31 Mar 2021 14:26:03
User entered '36.7' C	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:09:20

US3372184

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:04:58
User signature succeeded.	Mira Baron (b) (4)	31 Mar 2021 14:26:03
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:09:20

US3372184

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:04:58
User signature succeeded.	Mira Baron (b) (4)	31 Mar 2021 14:26:03
User entered 'Forehead'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:09:20

US3372184

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:04:58
User signature succeeded.	Mira Baron (b) (4)	31 Mar 2021 14:26:03
User entered '60'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:09:20

US3372184

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:04:58
User entered 'bpm'	System	30 Mar 2021 20:09:20

US3372184

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:04:58
User signature succeeded.	Mira Baron (b) (4)	31 Mar 2021 14:26:03
User entered '17'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:09:20

US3372184

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:04:58
User entered 'breaths/min'	System	30 Mar 2021 20:09:20

US3372184

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:04:58
User signature succeeded.	Mira Baron (b) (4)	31 Mar 2021 14:26:03
User entered '120'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:09:20

US3372184

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:04:58
User entered 'mmHg'	System	30 Mar 2021 20:09:20

US3372184

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:04:58
User signature succeeded.	Mira Baron (b) (4)	31 Mar 2021 14:26:03
User entered '66'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 20:09:20

US3372184

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:04:58
User entered 'mmHg'	System	30 Mar 2021 20:09:20

US3372184

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:04:58

US3372184

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:04:58

US3372184

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:14:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:04:58
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:21:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:12:44

US3372184

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:14:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:04:58
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:21:44
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:12:44

US3372184

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:04:58
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:21:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:13:00

US3372184

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:04:58
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:21:44
User entered '15 Mar 2021'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:13:00

US3372184

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:43

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:04:58
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:21:44
User entered '14:23'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:13:00

US3372184

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:04:58
User entered '15 Mar 2021 14:23'	System	16 Mar 2021 15:13:00

US3372184

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:04:58
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:21:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:13:03

US3372184

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:04:58
User entered 'I'	System	16 Mar 2021 15:13:03

US3372184

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	20 Apr 2021 18:29:13
	(b) (4)	
User entered 'Yes (Y)'	Danielle Theodore (b) (4)	20 Apr 2021 16:35:37
	(b) (4)	

US3372184

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	20 Apr 2021 18:29:13
	(b) (4)	
User entered '20 Apr 2021'	Danielle Theodore (b) (4)	20 Apr 2021 16:35:37
	(b) (4)	

US3372184

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	20 Apr 2021 18:29:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	20 Apr 2021 16:35:37

US3372184

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	20 Apr 2021 18:29:13
User entered empty.	(b) (4)	
	Danielle Theodore (b) (4)	20 Apr 2021 16:35:37
	(b) (4)	

US3372184

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	20 Apr 2021 18:29:13
	(b) (4)	
User entered 'Yes (Y)'	Danielle Theodore (b) (4)	20 Apr 2021 16:35:44
	(b) (4)	

US3372184

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:43

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Apr 2021 16:35:44

US3372184

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

Form: Visit Date

Generated On: 09 Jun 2021 17:14:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:11:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:51:44

US3372184

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

Form: Visit Date

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:11:53
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:51:44

US3372184

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

Form: Visit Date

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:11:53
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:51:44

US3372184

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

Form: Visit Date

Generated On: 09 Jun 2021 17:14:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User entered 'UNBLND_DECIDE'	System	19 Jan 2021 16:51:44

US3372184

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

Form: Unblinding

Generated On: 09 Jun 2021 17:14:43

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:57:15
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:52:04

US3372184

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

Form: Unblinding

Generated On: 09 Jun 2021 17:14:43

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 18:06:56
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 14:29:20
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:08:34

US3372184

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

Form: Unblinding

Generated On: 09 Jun 2021 17:14:43

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:57:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:52:04

US3372184

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

Form: Unblinding

Generated On: 09 Jun 2021 17:14:43

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
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.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 23:14:09
User signature succeeded.	Mira Baron (b) (4)	14 Apr 2021 18:06:56
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.' answered with 'data updated' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 14:29:23
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	14 Apr 2021 14:29:20
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.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 16:19:51
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:08:34

US3372184

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

Form: Unblinding

Generated On: 09 Jun 2021 17:14:43

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:57:15
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:52:04

US3372184

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

Form: Unblinding

Generated On: 09 Jun 2021 17:14:43

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:57:15
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:52:04

US3372184

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

Form: Unblinding

Generated On: 09 Jun 2021 17:14:43

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:57:15
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 12:20:00
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	19 Jan 2021 16:52:04

US3372184

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

Form: Unblinding

Generated On: 09 Jun 2021 17:14:43

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:57:15
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 12:20:00
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	19 Jan 2021 16:52:04

US3372184

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

Form: Unblinding

Generated On: 09 Jun 2021 17:14:43

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:57:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:52:04

US3372184

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

Form: Unblinding

Generated On: 09 Jun 2021 17:14:43

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User entered '1'	System	19 Jan 2021 16:52:04

US3372184

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

Form: Unblinding

Generated On: 09 Jun 2021 17:14:43

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User entered 'I'	System	19 Jan 2021 16:52:04

US3372184

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:14:43

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:16
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:54:09

US3372184

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:14:43

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:16
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:54:09

US3372184

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:14:43

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:16
User entered empty.	System	19 Jan 2021 16:54:09
DataPoint set to visible.	System	19 Jan 2021 16:52:04

US3372184

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:14:43

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:16
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:54:09

US3372184

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:14:43

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:16
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:54:09

US3372184

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:14:43

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:16
User entered empty.	System	19 Jan 2021 16:54:09
DataPoint set to visible.	System	19 Jan 2021 16:52:04

US3372184

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:16
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	19 Jan 2021 16:54:09

US3372184

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:16
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:54:09

US3372184

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:16
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:54:09

US3372184

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:16
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered '14:50'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:54:09

US3372184

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:16
User entered '14 Jan 2021 14:50'	System	19 Jan 2021 16:54:09

US3372184

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:16
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered '36.6' C	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:54:09

US3372184

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:16
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:54:09

US3372184

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:16
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered 'FOREHEAD'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:54:09

US3372184

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:16
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
	(b) (4)	
User closed query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	20 Jan 2021 15:44:37
Query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	20 Jan 2021 15:44:37
User entered '75' reason for change: Data Entry Error	Peter Jacob (b) (4)	20 Jan 2021 15:44:37
	(b) (4)	
User opened query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	19 Jan 2021 16:54:09
User entered '160'	(b) (4), (b) (6)	19 Jan 2021 16:54:09

US3372184

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:16
User entered 'bpm'	System	19 Jan 2021 16:54:09

US3372184

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:16
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered '17'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:54:09

US3372184

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:16
User entered 'breaths/min'	System	19 Jan 2021 16:54:09

US3372184

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:16
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered '160'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:54:09

US3372184

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:16
User entered 'mmHg'	System	19 Jan 2021 16:54:09

US3372184

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:16
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered '90'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:54:09

US3372184

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:16
User entered 'mmHg'	System	19 Jan 2021 16:54:09

US3372184

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:14:43

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:16
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:54:09

US3372184

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:14:43

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:16
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:54:09

US3372184

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:14:43

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:16
User entered empty.	System	19 Jan 2021 16:54:09
DataPoint set to visible.	System	19 Jan 2021 16:52:04

US3372184

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:16
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	19 Jan 2021 16:54:09

US3372184

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:16
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:54:09

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:16
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:54:09

US3372184

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:16
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered '16:30'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:54:09

US3372184

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:16
User entered '14 Jan 2021 16:30'	System	19 Jan 2021 16:54:09

US3372184

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:16
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered '36.7' C	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:54:09

US3372184

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:16
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:54:09

US3372184

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:16
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered 'FOREHEAD'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:54:09

US3372184

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:16
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered '59'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:54:09

US3372184

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:16
User entered 'bpm'	System	19 Jan 2021 16:54:09

US3372184

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:16
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered '16'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:54:09

US3372184

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:16
User entered 'breaths/min'	System	19 Jan 2021 16:54:09

US3372184

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:16
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered '158'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:54:09

US3372184

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:16
User entered 'mmHg'	System	19 Jan 2021 16:54:09

US3372184

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:16
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered '90'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:54:09

US3372184

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:16
User entered 'mmHg'	System	19 Jan 2021 16:54:09

US3372184

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:14:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:05:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:54:44

US3372184

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:14:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:05:56
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:54:44

US3372184

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

Form: Exposure

Generated On: 09 Jun 2021 17:14:43

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:39:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:55:21

US3372184

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

Form: Exposure

Generated On: 09 Jun 2021 17:14:43

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:39:55
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:55:21

US3372184

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

Form: Exposure

Generated On: 09 Jun 2021 17:14:43

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)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:39:55
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:55:21

US3372184

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

Form: Exposure

Generated On: 09 Jun 2021 17:14:43

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User entered 'mRNA-1273'	System	19 Jan 2021 16:55:21
DataPoint set to visible.	System	19 Jan 2021 16:52:04

US3372184

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

Form: Exposure

Generated On: 09 Jun 2021 17:14:43

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:39:55
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:55:21

US3372184

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

Form: Exposure

Generated On: 09 Jun 2021 17:14:43

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:39:55
User entered '15:14'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:55:21

US3372184

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

Form: Exposure

Generated On: 09 Jun 2021 17:14:43

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User entered '14 Jan 2021 15:14'	System	19 Jan 2021 16:55:21

US3372184

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

Form: Exposure

Generated On: 09 Jun 2021 17:14:43

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:39:55
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:55:21

US3372184

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

Form: Exposure

Generated On: 09 Jun 2021 17:14:43

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User entered 'ONCE'	System	19 Jan 2021 16:55:21

US3372184

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

Form: Exposure

Generated On: 09 Jun 2021 17:14:43

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User entered 'INTRAMUSCULAR'	System	19 Jan 2021 16:55:21

US3372184

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:01:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:52:15

US3372184

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:01:40
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:52:15

US3372184

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:43

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 00:01:40
User entered '14:14'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:52:15

US3372184

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User entered '14 Jan 2021 14:14'	System	19 Jan 2021 16:52:15

US3372184

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:14:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:34:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:52:26

US3372184

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:14:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:34:24
User entered '14 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:52:26

US3372184

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:14:43

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 17:34:24
User entered '14:11'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:52:26

US3372184

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:14:43

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User entered '14 Jan 2021 14:11'	System	19 Jan 2021 16:52:26

US3372184

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

Form: Continuing

Generated On: 09 Jun 2021 17:14:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:33:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 16:52:29

US3372184

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

Form: Continuing

Generated On: 09 Jun 2021 17:14:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User entered 'I'	System	19 Jan 2021 16:52:29

US3372184

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:16
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:32:59
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	21 Jan 2021 16:58:57
	(b) (4)	

US3372184

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:43

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:16
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:32:59
User entered '21 Jan 2021'	(b) (4) Danielle Theodore (b) (4)	21 Jan 2021 16:58:57
	(b) (4)	

US3372184

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:16
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:32:59
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4)	21 Jan 2021 16:58:57

US3372184

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:16
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:32:59
User entered empty.	(b) (4) Danielle Theodore (b) (4)	21 Jan 2021 16:58:57
	(b) (4)	

US3372184

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:16
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:33:34
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	21 Jan 2021 16:59:02

US3372184

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:16
User entered 'I'	System	21 Jan 2021 16:59:02

US3372184

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:43

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:16
User entered '1'	System	21 Jan 2021 16:59:02
DataPoint set to visible.	System	21 Jan 2021 16:59:02

US3372184

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:14:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:11:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 17:55:32

US3372184

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:11:53
User entered '12 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 17:55:32

US3372184

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:11:53
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 17:55:32

US3372184

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:14:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User entered 'OLD29'	System	15 Feb 2021 17:55:32

US3372184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	15 Feb 2021 17:56:39

US3372184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 17:56:39

US3372184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered '12 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 17:56:39

US3372184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered '12:15'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 17:56:39

US3372184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User entered '12 Feb 2021 12:15'	System	15 Feb 2021 17:56:39

US3372184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered '36.6' C	(b) (4) (b) (4), (b) (6)	15 Feb 2021 17:56:39

US3372184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 17:56:39

US3372184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered 'FOREHEAD'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 17:56:39

US3372184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered '60'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 17:56:39

US3372184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User entered 'bpm'	System	15 Feb 2021 17:56:39

US3372184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered '17'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 17:56:39

US3372184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User entered 'breaths/min'	System	15 Feb 2021 17:56:39

US3372184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered '159'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 17:56:39

US3372184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User entered 'mmHg'	System	15 Feb 2021 17:56:39

US3372184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered '90'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 17:56:39

US3372184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:14:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User entered 'mmHg'	System	15 Feb 2021 17:56:39

US3372184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	15 Feb 2021 17:56:39

US3372184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 17:56:39

US3372184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered '12 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 17:56:39

US3372184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered '13:18'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 17:56:39

US3372184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User entered '12 Feb 2021 13:18'	System	15 Feb 2021 17:56:39

US3372184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered '36.7' C	(b) (4) (b) (4), (b) (6)	15 Feb 2021 17:56:39

US3372184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 17:56:39

US3372184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered 'FOREHEAD'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 17:56:39

US3372184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered '60'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 17:56:39

US3372184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User entered 'bpm'	System	15 Feb 2021 17:56:39

US3372184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered '18'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 17:56:39

US3372184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User entered 'breaths/min'	System	15 Feb 2021 17:56:39

US3372184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered '150'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 17:56:39

US3372184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User entered 'mmHg'	System	15 Feb 2021 17:56:39

US3372184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 03:44:35
User entered '83'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 17:56:39

US3372184

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:14:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User entered 'mmHg'	System	15 Feb 2021 17:56:39

US3372184

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:14:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:05:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 17:56:43

US3372184

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:14:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:05:56
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 17:56:43

US3372184

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:14:43

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:39:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 17:56:55

US3372184

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:14:43

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:39:55
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 17:56:55

US3372184

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:14:43

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)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:39:55
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Feb 2021 17:56:55

US3372184

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:14:43

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User entered 'mRNA-1273'	System	15 Feb 2021 17:56:55
DataPoint set to visible.	System	21 Jan 2021 16:59:02

US3372184

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:14:43

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:39:55
User entered '12 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 17:56:55

US3372184

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:14:43

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:39:55
User entered '12:45'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 17:56:55

US3372184

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:14:43

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User entered '12 Feb 2021 12:45'	System	15 Feb 2021 17:56:55

US3372184

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:14:43

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 23:39:55
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 17:56:55

US3372184

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:14:43

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User entered 'ONCE'	System	15 Feb 2021 17:56:55

US3372184

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:14:43

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User entered 'INTRAMUSCULAR'	System	15 Feb 2021 17:56:55

US3372184

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:33:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 17:57:00

US3372184

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User entered 'I'	System	15 Feb 2021 17:57:00

US3372184

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:43

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:16
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:28:55
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4)	19 Feb 2021 21:00:40

US3372184

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:16
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:28:55
User entered '19 Feb 2021'	(b) (4) Danielle Theodore (b) (4) (b) (4)	19 Feb 2021 21:00:40

US3372184

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:43

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:16
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:28:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Danielle Theodore (b) (4)	19 Feb 2021 21:00:40
	(b) (4)	

US3372184

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:14:43

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:16
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:28:55
User entered empty.	(b) (4) Danielle Theodore (b) (4)	19 Feb 2021 21:00:40
	(b) (4)	

US3372184

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:16
User signature succeeded.	Mira Baron (b) (4)	19 Feb 2021 22:28:55
User entered 'Yes (Y)'	(b) (4) Danielle Theodore (b) (4) (b) (4)	19 Feb 2021 21:00:49

US3372184

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:14:43

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:16
User entered 'I'	System	19 Feb 2021 21:00:49

US3372184

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:14:43

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:21:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:11:28

US3372184

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:21:44
User entered '15 Mar 2021'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:11:28

US3372184

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:21:44
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:11:28

US3372184

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:14:43

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User entered 'OLD57'	System	16 Mar 2021 15:11:28

US3372184

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User closed query ' Per CDM:Please be aware that Visit 4 and OL-D57 took place exactly the same day. However, "Vital signs" has no response of "Yes" or "No", but on OL-D57 it is recorded as "Yes". Please clarify why there is a difference or update the field. Thank you!' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 15:27:57
Query ' Per CDM:Please be aware that Visit 4 and OL-D57 took place exactly the same day. However, "Vital signs" has no response of "Yes" or "No", but on OL-D57 it is recorded as "Yes". Please clarify why there is a difference or update the field. Thank you!' answered with 'Data updated.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 20:09:31
User opened query ' Per CDM:Please be aware that Visit 4 and OL-D57 took place exactly the same day. However, "Vital signs" has no response of "Yes" or "No", but on OL-D57 it is recorded as "Yes". Please clarify why there is a difference or update the field. Thank you!' (Site from DM).	(b) (4), (b) (6)	28 Mar 2021 10:37:22
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:21:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Mar 2021 15:11:55

US3372184

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:21:44
User entered '15 Mar 2021'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:11:55

US3372184

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:21:44
User entered '13:52'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:11:55

US3372184

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User entered '15 Mar 2021 13:52'	System	16 Mar 2021 15:11:55

US3372184

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:21:44
User entered '36.7' C	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:11:55

US3372184

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:21:44
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:11:55

US3372184

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:21:44
User entered 'FOREHEAD'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:11:55

US3372184

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:21:44
User entered '60'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:11:55

US3372184

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User entered 'bpm'	System	16 Mar 2021 15:11:55

US3372184

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:21:44
User entered '17'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:11:55

US3372184

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User entered 'breaths/min'	System	16 Mar 2021 15:11:55

US3372184

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:21:44
User entered '120'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:11:55

US3372184

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User entered 'mmHg'	System	16 Mar 2021 15:11:55

US3372184

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:21:44
User entered '66'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:11:55

US3372184

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User entered 'mmHg'	System	16 Mar 2021 15:11:55

US3372184

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06

US3372184

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:14:43

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06

US3372184

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:14:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:21:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:12:01

US3372184

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:14:43

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:21:44
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:12:01

US3372184

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:20:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:12:14

US3372184

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:20:40
User entered '15 Mar 2021'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:12:14

US3372184

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:43

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:20:40
User entered '14:23'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 15:12:14

US3372184

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:14:43

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:40:06
User entered '15 Mar 2021 14:23'	System	16 Mar 2021 15:12:14

US3372184

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:14:43

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:06:13
User closed query 'Per DM CLR: Per Day 215 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 15:28:18
Query 'Per DM CLR: Per Day 215 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'Subject had no AEs to report within this time frame.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 18:13:28
User opened query 'Per DM CLR: Per Day 215 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 10:47:55
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 16:45:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 13:31:15
User entered 'Yes (Y)'	Elena Acosta (b) (4) (b) (4)	03 Sep 2020 14:46:31

US3372184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:43

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Sep 2020 13:31:32
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:30
User entered	System	07 Sep 2020 16:55:11
'USA-US056-2020-mRNA-1273-P301000002'		
User entered 'New'	(b) (4), (b) (6)	07 Sep 2020 16:55:11

US3372184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:43

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 13:31:32
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Appendicitis, LLT: Appendicitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 17:05:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Sep 2020 17:05:48
Data point term sent to Coder	System	03 Sep 2020 17:05:04
User entered 'Appendicitis'	Elena Acosta (b) (4) (b) (4)	03 Sep 2020 17:04:23

US3372184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:45:30
User closed query 'Per sponsor review, SAE resulted in inpatient hospitalization. Please update field accordingly.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 06:19:06
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
Query 'Per sponsor review, SAE resulted in inpatient hospitalization. Please update field accordingly.' answered with 'data updated' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 17:39:05
DataPoint Un-verified.	(b) (4), (b) (6)	24 Feb 2021 17:38:56
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 17:38:56
User opened query 'Per sponsor review, SAE resulted in inpatient hospitalization. Please update field accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 14:58:22
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 13:31:32
User entered 'No (N)'	Elena Acosta (b) (4)	03 Sep 2020 17:04:23

US3372184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 13:31:32
User entered 'No (N)'	Elena Acosta (b) (4) (b) (4)	03 Sep 2020 17:04:23

US3372184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 13:31:32
User entered 'No (N)'	Elena Acosta (b) (4) (b) (4)	03 Sep 2020 17:04:23

US3372184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 21:46:45
User closed query 'Please enter correct date format. 02Sep2020.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 21:46:43
Query 'Please enter correct date format. 02Sep2020.' answered with 'corrected' (Site from CRA).	Mary Sergalis (b) (4)	10 Nov 2020 21:44:26
User entered '02 Sep 2020' reason for change: Data Entry Error	Mary Sergalis (b) (4)	10 Nov 2020 21:44:17
User opened query 'Please enter correct date format. 02Sep2020.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:33:18
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 19:32:38
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 13:31:32
User entered '2 Sep 2020'	Elena Acosta (b) (4)	03 Sep 2020 17:04:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:43

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 13:31:32
User entered empty.	Elena Acosta (b) (4) (b) (4)	03 Sep 2020 17:04:23

US3372184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 17:04:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 13:31:32
User entered 'No (N)'	Elena Acosta (b) (4) (b) (4)	03 Sep 2020 17:04:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 21:47:10
User closed query 'Please enter correct date format. 02Sep2020.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 21:47:07
Query 'Please enter correct date format. 02Sep2020.' answered with 'corrected' (Site from CRA).	Mary Sergalis (b) (4)	10 Nov 2020 21:44:58
User entered '02 Sep 2020' reason for change: Data Entry Error	Mary Sergalis (b) (4)	10 Nov 2020 21:44:47
User opened query 'Please enter correct date format. 02Sep2020.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:33:42
DataPoint Un-verified.	(b) (4), (b) (6)	10 Nov 2020 19:33:33
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 16:00:18
User closed query 'PV query: Please provide the event end date when available. Please do not response to this query until the event has ended. ' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 15:07:04
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	19 Oct 2020 18:45:32
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	19 Oct 2020 18:45:32
Query 'PV query: Please provide the event end date when available. Please do not response to this query until the event has ended. ' answered with 'added' (Site from Safety).	Mary Sergalis (b) (4)	19 Oct 2020 18:44:14
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	19 Oct 2020 18:43:46
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	19 Oct 2020 18:43:46
DataPoint Un-verified.	Mary Sergalis (b) (4)	19 Oct 2020 18:43:46

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '2 Sep 2020' reason for change: Data Entry Error	Mary Sergalis (b) (4)	19 Oct 2020 18:43:46
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 13:31:32
User opened query 'PV query: Please provide the event end date when available. Please do not response to this query until the event has ended. ' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 13:24:55
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	03 Sep 2020 17:05:22
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	03 Sep 2020 17:05:22
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	03 Sep 2020 17:05:22
User entered empty; reason for change Data Entry Error	Elena Acosta (b) (4)	03 Sep 2020 17:05:22
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	03 Sep 2020 17:04:23
User entered '2 Sep 2020'	Elena Acosta (b) (4)	03 Sep 2020 17:04:23

US3372184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:43

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 13:31:32
User entered empty.	Elena Acosta (b) (4) (b) (4)	03 Sep 2020 17:04:23

US3372184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Sep 2020 17:04:23

US3372184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:43

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 15:58:10
User closed query 'PV query: Please confirm if the event was life-threatening (the subject was at risk of death at the time of the event) as the severity was reported as grade 4. If yes, please provide additional information (i.e ruptured appendix, peritonitis, etc) If not, please consider changing to grade 3. ' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 15:07:26
Query 'PV query: Please confirm if the event was life-threatening (the subject was at risk of death at the time of the event) as the severity was reported as grade 4. If yes, please provide additional information (i.e ruptured appendix, peritonitis, etc) If not, please consider changing to grade 3. ' answered with 'Not life threatening. Severity changed ' (Site from Safety).	Mary Sergalis (b) (4)	19 Oct 2020 18:44:44
DataPoint Un-verified.	Mary Sergalis (b) (4)	19 Oct 2020 18:43:46
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Mary Sergalis (b) (4)	19 Oct 2020 18:43:46
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 13:31:32
User opened query 'PV query: Please confirm if the event was life-threatening (the subject was at risk of death at the time of the event) as the severity was reported as grade 4. If yes, please provide additional information (i.e ruptured appendix, peritonitis, etc) If not, please consider changing to grade 3. ' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 13:23:53
User entered 'Grade 4 (Grade 4)'	Elena Acosta (b) (4) (b) (4)	03 Sep 2020 17:04:23

US3372184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 13:31:32
User entered 'Yes (Y)'	Elena Acosta (b) (4) (b) (4)	03 Sep 2020 17:04:23

US3372184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 13:31:32
User entered '0'	Elena Acosta (b) (4) (b) (4)	03 Sep 2020 17:04:23

US3372184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 13:31:32
User entered '0'	Elena Acosta (b) (4) (b) (4)	03 Sep 2020 17:04:23

US3372184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:43

Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User closed query 'PV Query: Please remove the seriousness criteria hospitalization as the visit was less than 24 hours. Please keep admission and discharge date in the narrative.' (Site from Safety). Query 'PV Query: Please remove the seriousness criteria hospitalization as the visit was less than 24 hours. Please keep admission and discharge date in the narrative.' answered with 'Subject was admitted for removal of the appendix thus it was greater than 24 hrs but this event ended when they had the surgery!' (Site from Safety).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:07:11
User opened query 'PV Query: Please remove the seriousness criteria hospitalization as the visit was less than 24 hours. Please keep admission and discharge date in the narrative.'	Mary Sergalis (b) (4)	02 Nov 2020 21:29:33
User opened query 'PV Query: Please remove the seriousness criteria hospitalization as the visit was less than 24 hours. Please keep admission and discharge date in the narrative.' (Site from Safety). Query 'Per CDM: Response is noted; However, discharge date is required. Please try and consider to collect the discharge date as the subject is still in the study. Thank you.' canceled (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:41:40
User opened query 'Per CDM: Response is noted; However, discharge date is required. Please try and consider to collect the discharge date as the subject is still in the study. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 16:24:42
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	18 Sep 2020 13:31:32
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Discharge date unknown, correct as entered ' (Site from System).	(b) (4), (b) (6)	10 Sep 2020 08:19:55
	(b) (4), (b) (6)	10 Sep 2020 08:12:00
	Elena Acosta (b) (4)	03 Sep 2020 17:06:49
	(b) (4)	

US3372184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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). User entered 'I'	System	03 Sep 2020 17:04:23
	Elena Acosta (b) (4) (b) (4)	03 Sep 2020 17:04:23

US3372184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:36:19
DataPoint Un-verified.	Mary Sergalis (b) (4)	10 Nov 2020 17:43:00
User entered '02 Sep 2020' reason for change: Data Entry Error	Mary Sergalis (b) (4)	10 Nov 2020 17:43:00
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 13:31:32
User entered '2 Sep 2020'	Elena Acosta (b) (4) (b) (4)	03 Sep 2020 17:04:23

US3372184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:14:43

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 21:36:21
User closed query 'Please verify date, noted in hospital records as 06Sept2020.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 21:36:16
Query 'Please verify date, noted in hospital records as 06Sept2020.' answered with 'corrected' (Site from CRA).	Mary Sergalis (b) (4)	10 Nov 2020 17:43:58
User entered '06 Sep 2020' reason for change: Data Entry Error	Mary Sergalis (b) (4)	10 Nov 2020 17:43:44
User opened query 'Please verify date, noted in hospital records as 06Sept2020.' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 21:03:13
DataPoint Un-verified.	Mary Sergalis (b) (4)	02 Nov 2020 21:33:22
User entered '07 Sep 2020' reason for change: Data Entry Error	Mary Sergalis (b) (4)	02 Nov 2020 21:33:22
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:18:26
User closed query 'Please verify, noted as 02Sept2020 in source note dated 22 Sept2020.' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 16:18:24
Query 'Please verify, noted as 02Sept2020 in source note dated 22 Sept2020.' answered with 'Corrected' (Site from CRA).	Mary Sergalis (b) (4)	26 Oct 2020 16:29:15
User entered '2 Sep 2020' reason for change: Data Entry Error	Mary Sergalis (b) (4)	26 Oct 2020 16:29:04
User opened query 'Please verify, noted as 02Sept2020 in source note dated 22 Sept2020.' (Site from CRA).	(b) (4), (b) (6)	26 Oct 2020 15:59:57
User closed query 'PV query: Please provide the discharge date, when available. ' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 15:08:06
Query 'PV query: Please provide the discharge date, when available. ' answered with 'added' (Site from Safety).	Mary Sergalis (b) (4)	19 Oct 2020 18:44:57
DataPoint Un-verified.	Mary Sergalis (b) (4)	19 Oct 2020 18:43:46

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Folder: Adverse Events

Form: Adverse Events (1)

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Sep 2020' reason for change: Data Entry Error	Mary Sergalis (b) (4)	19 Oct 2020 18:43:46
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 13:31:32
User opened query 'PV query: Please provide the discharge date, when available. ' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 13:25:21
User entered empty.	Elena Acosta (b) (4)	03 Sep 2020 17:04:23

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 13:31:32
User entered 'No (N)'	Elena Acosta (b) (4) (b) (4)	03 Sep 2020 17:04:23

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 13:31:32
User entered empty.	Elena Acosta (b) (4) (b) (4)	03 Sep 2020 17:04:23

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 13:31:32
User entered '0'	Elena Acosta (b) (4) (b) (4)	03 Sep 2020 17:04:23

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 13:31:32
User entered '0'	Elena Acosta (b) (4) (b) (4)	03 Sep 2020 17:04:23

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 13:31:32
User entered '0'	Elena Acosta (b) (4) (b) (4)	03 Sep 2020 17:04:23

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 13:31:32
User entered 'Not Related (NOT RELATED)'	Elena Acosta (b) (4) (b) (4)	03 Sep 2020 17:04:23

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 13:31:32
User entered 'Not Related (NOT RELATED)'	(b) (4) Elena Acosta (b) (4) (b) (4)	03 Sep 2020 17:04:23

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Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:45:42
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:20:40
User closed query 'Per CDM: Action taken with investigational product is recorded as "Not Applicable" ,however, ae start date is between the two IP dose dates. Per CCGs p. 51, Action taken with investigational product is expected to be "Not Applicable" only when adverse event started after last of dose of IP or before first dose of investigational product. Kindly review and reconcile as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 14:05:33
Query 'Per CDM: Action taken with investigational product is recorded as "Not Applicable" ,however, ae start date is between the two IP dose dates. Per CCGs p. 51, Action taken with investigational product is expected to be "Not Applicable" only when adverse event started after last of dose of IP or before first dose of investigational product. Kindly review and reconcile as appropriate. ' answered with 'Data updated.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 19:14:05
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 19:13:54
Signature has been broken.	(b) (4), (b) (6)	05 Mar 2021 19:13:54
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 19:13:54
User opened query 'Per CDM: Action taken with investigational product is recorded as "Not Applicable" ,however, ae start date is between the two IP dose dates. Per CCGs p. 51, Action taken with investigational product is expected to be "Not Applicable" only when adverse event started after last of dose of IP or before first dose of investigational product. Kindly review and reconcile as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 04:05:28
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User closed query 'PV Query: Apologies for the confusion as action taken was correct as not applicable. Please change back.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:07:19

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Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 16:37:19
Query 'PV Query: Apologies for the confusion as action taken was correct as not applicable. Please change back.' answered with 'updated' (Site from Safety).	Mary Sergalis (b) (4)	02 Nov 2020 21:33:36
DataPoint Un-verified.	Mary Sergalis (b) (4)	02 Nov 2020 21:33:22
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Mary Sergalis (b) (4)	02 Nov 2020 21:33:22
User opened query 'PV Query: Apologies for the confusion as action taken was correct as not applicable. Please change back.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 19:41:04
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 16:00:49
User closed query 'PV Query: Please consider updating action taken from not applicable as patient received study drug prior to event onset. ' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 15:09:34
Query 'PV Query: Please consider updating action taken from not applicable as patient received study drug prior to event onset. ' answered with 'updated' (Site from Safety).	Mary Sergalis (b) (4)	19 Oct 2020 18:45:07
DataPoint Un-verified.	Mary Sergalis (b) (4)	19 Oct 2020 18:43:46
User entered 'None (NONE)' reason for change: Data Entry Error	Mary Sergalis (b) (4)	19 Oct 2020 18:43:46
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 13:31:32
User opened query 'PV Query: Please consider updating action taken from not applicable as patient received study drug prior to event onset. ' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 13:45:21
User entered 'Not Applicable (NOT APPLICABLE)'	Elena Acosta (b) (4)	03 Sep 2020 17:04:23

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 13:31:32
User entered '0'	Elena Acosta (b) (4) (b) (4)	03 Sep 2020 17:04:23

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:02:07
User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so. ' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 15:11:24
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so. ' answered with 'they are already added' (Site from Safety).	Mary Sergalis (b) (4)	19 Oct 2020 18:48:40
DataPoint Un-verified.	Mary Sergalis (b) (4)	19 Oct 2020 18:47:52
User entered '1' reason for change: Data Entry Error	Mary Sergalis (b) (4)	19 Oct 2020 18:47:52
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 13:31:32
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so. ' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 13:43:50
User entered '0'	Elena Acosta (b) (4) (b) (4)	03 Sep 2020 17:04:23

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Oct 2020 08:11:02
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'added' (Site from DM).	Mary Sergalis (b) (4)	19 Oct 2020 18:51:59
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 02:36:39
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 13:31:32
User entered 'I'	Elena Acosta (b) (4) (b) (4)	03 Sep 2020 17:04:23

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 16:01:08
User closed query 'PV query: Please provide the final outcome, when available. Please do not response to this query until the event has ended. ' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 15:14:15
Query 'PV query: Please provide the final outcome, when available. Please do not response to this query until the event has ended. ' answered with 'added' (Site from Safety).	Mary Sergalis (b) (4)	19 Oct 2020 18:52:10
DataPoint Un-verified.	Mary Sergalis (b) (4)	19 Oct 2020 18:45:32
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Mary Sergalis (b) (4)	19 Oct 2020 18:45:32
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 13:31:32
User opened query 'PV query: Please provide the final outcome, when available. Please do not response to this query until the event has ended. ' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 13:24:35
User entered 'Unknown (UNKNOWN)'	Elena Acosta (b) (4)	03 Sep 2020 17:04:23
	(b) (4)	

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 13:31:32
User entered empty.	Elena Acosta (b) (4) (b) (4)	03 Sep 2020 17:04:23

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User closed query 'PV Query: Please provide the pathology results of the appendix that was removed in surgery. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 18:07:26
User closed query 'PV Query: Please provide the signs and symptoms exhibited by the subject.' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 18:07:24
Query 'PV Query: Please provide the pathology results of the appendix that was removed in surgery. ' answered with 'Not available' (Site from Safety).	Mary Sergalis (b) (4)	02 Nov 2020 21:34:03
Query 'PV Query: Please provide the signs and symptoms exhibited by the subject.' answered with 'abdominal pain' (Site from Safety).	Mary Sergalis (b) (4)	02 Nov 2020 21:33:50
User opened query 'PV Query: Please provide the pathology results of the appendix that was removed in surgery. ' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 19:40:44
User opened query 'PV Query: Please provide the signs and symptoms exhibited by the subject.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 19:40:19
User closed query 'PV Query: Please provide the pathology results of the appendix that was removed in surgery.' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 15:16:07
User closed query 'PV Query: Please provide the signs and symptoms exhibited by the subject.' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 15:15:55
User closed query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 15:15:31
User closed query 'PV Query: Please provide any additional treatment given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no additional treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	20 Oct 2020 15:15:20
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)	20 Oct 2020 15:14:22

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the signs and symptoms exhibited by the subject.' answered with 'Pain' (Site from Safety).	Mary Sergalis (b) (4)	19 Oct 2020 18:55:55
Query 'PV Query: Please provide the pathology results of the appendix that was removed in surgery.' answered with 'Unknown. Not received with medical records' (Site from Safety).	Mary Sergalis (b) (4)	19 Oct 2020 18:55:26
Query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' answered with 'This was already added if you had checked medical history page' (Site from Safety).	Mary Sergalis (b) (4)	19 Oct 2020 18:54:52
Query 'PV Query: Please provide any additional treatment given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no additional treatment was provided, please state so. ' answered with 'treatments have already been added' (Site from Safety).	Mary Sergalis (b) (4)	19 Oct 2020 18:53:29
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' answered with 'No relevant laboratory results' (Site from Safety).	Mary Sergalis (b) (4)	19 Oct 2020 18:53:06
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 13:31:32
User opened query 'PV Query: Please provide the pathology results of the appendix that was removed in surgery.' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 12:09:35
User opened query 'PV Query: Please provide the signs and symptoms exhibited by the subject.' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 13:44:53
User opened query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 13:44:36

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any additional treatment given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no additional treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	11 Sep 2020 13:44:11
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)	11 Sep 2020 13:43:21
User entered 'Subject contacted the site and was admitted to the Hospital 09/02/2020, with Acute Appendicitis, had Appendectomy performed same day.'	Elena Acosta (b) (4)	03 Sep 2020 17:04:23

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 Sep 2020 17:04:23

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Feb 2021 17:38:56
User entered '0'	System	03 Sep 2020 17:04:23

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 Sep 2020 17:04:23

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:37

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Folder: Adverse Events

Form: Adverse Events (2)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:37
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain lower, LLT: Right lower quadrant pain - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 19:51:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 19:51:53
Data point term sent to Coder	System	16 Nov 2020 19:51:13
User entered 'Right Lower Abdominal Pain'	Mary Sergalis (b) (4)	16 Nov 2020 19:50:55

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Folder: Adverse Events

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:37
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User entered 'Yes (Y)'	(b) (4) Mary Sergalis (b) (4)	16 Nov 2020 19:50:55

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Folder: Adverse Events

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:37
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	16 Nov 2020 19:50:55

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:37
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	16 Nov 2020 19:50:55

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:37
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User entered '28 Aug 2020'	(b) (4) Mary Sergalis (b) (4)	16 Nov 2020 19:50:55

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[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:37
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User entered empty.	(b) (4) Mary Sergalis (b) (4)	16 Nov 2020 19:50:55

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:37
User entered empty.	System	16 Nov 2020 19:50:55

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:37
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	16 Nov 2020 19:50:55

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:37
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User entered '28 Aug 2020'	(b) (4) Mary Sergalis (b) (4)	16 Nov 2020 19:50:55

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[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:37
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User entered empty.	(b) (4) Mary Sergalis (b) (4)	16 Nov 2020 19:50:55

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:37
User entered empty.	System	16 Nov 2020 19:50:55

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Folder: Adverse Events

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:37
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Mary Sergalis (b) (4)	16 Nov 2020 19:50:55

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:37
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User entered 'No (N)'	(b) (4) Mary Sergalis (b) (4)	16 Nov 2020 19:50:55

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Folder: Adverse Events

Form: Adverse Events (2)

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:37
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User entered '0'	(b) (4) Mary Sergalis (b) (4)	16 Nov 2020 19:50:55

US3372184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:43

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:37
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User entered '0'	(b) (4) Mary Sergalis (b) (4)	16 Nov 2020 19:50:55

US3372184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:37
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User entered '0'	(b) (4) Mary Sergalis (b) (4)	16 Nov 2020 19:50:55

US3372184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:37
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User entered empty.	(b) (4) Mary Sergalis (b) (4)	16 Nov 2020 19:50:55

US3372184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:43

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:37
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User entered empty.	(b) (4) Mary Sergalis (b) (4)	16 Nov 2020 19:50:55

US3372184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:37
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User entered empty.	(b) (4) Mary Sergalis (b) (4)	16 Nov 2020 19:50:55

US3372184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:37
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User entered empty.	(b) (4) Mary Sergalis (b) (4)	16 Nov 2020 19:50:55

US3372184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:37
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User entered '0'	(b) (4) Mary Sergalis (b) (4)	16 Nov 2020 19:50:55

US3372184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:37
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User entered '0'	(b) (4) Mary Sergalis (b) (4)	16 Nov 2020 19:50:55

US3372184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:43

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:37
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User entered '0'	(b) (4) Mary Sergalis (b) (4)	16 Nov 2020 19:50:55

US3372184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:37
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User closed query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:46:40
Query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you' answered with 'AE is not related to study procedure.' (Site from DM).	Jennifer Torres (b) (4)	18 Nov 2020 17:56:44
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Jennifer Torres (b) (4)	18 Nov 2020 17:56:38
User opened query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 06:17:10
User entered 'Not Applicable (NOT APPLICABLE)'	Mary Sergalis (b) (4)	16 Nov 2020 19:50:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:37
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
	Mary Sergalis (b) (4)	16 Nov 2020 19:50:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:43

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:37
User closed query 'Per CDM: CCGs p. 34, Action taken with investigational product is expected to be "Not Applicable" if adverse event started after last of dose of IP or before first dose of investigational product. Kindly review and reconcile as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 06:19:54
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
Query 'Per CDM: CCGs p. 34, Action taken with investigational product is expected to be "Not Applicable" if adverse event started after last of dose of IP or before first dose of investigational product. Kindly review and reconcile as appropriate. ' answered with 'data updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:40:27
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Feb 2021 17:40:20
User opened query 'Per CDM: CCGs p. 34, Action taken with investigational product is expected to be "Not Applicable" if adverse event started after last of dose of IP or before first dose of investigational product. Kindly review and reconcile as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 10:52:30
User entered 'Not Applicable (NOT APPLICABLE)'	Mary Sergalis (b) (4)	16 Nov 2020 19:50:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:43

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:37
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	16 Nov 2020 19:51:13
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	16 Nov 2020 19:50:55
User entered '0'	Mary Sergalis (b) (4)	16 Nov 2020 19:50:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:37
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User entered '1' reason for change: Data Entry Error	(b) (4)	16 Nov 2020 19:51:13
User entered '0'	Mary Sergalis (b) (4)	16 Nov 2020 19:50:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:37
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User entered '0'	(b) (4) Mary Sergalis (b) (4)	16 Nov 2020 19:50:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:43

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:37
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Nov 2020 19:51:13
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Mary Sergalis (b) (4)	16 Nov 2020 19:51:13
Data Entry Error		
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 19:50:55
User entered empty.	Mary Sergalis (b) (4)	16 Nov 2020 19:50:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:43

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:37
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User entered empty.	(b) (4) Mary Sergalis (b) (4)	16 Nov 2020 19:50:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:43

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:37
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User entered empty.	(b) (4)	16 Nov 2020 19:50:55
	Mary Sergalis (b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:37
User entered '0'	System	16 Nov 2020 19:50:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:37
User entered 'I'	System	16 Nov 2020 19:50:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:14:43

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:37

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Folder: Adverse Events

Form: Adverse Events (3)

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27

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Folder: Adverse Events

Form: Adverse Events (3)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Diarrhoea (excl infective), PT: Diarrhoea, LLT: Loose stools - version MedDRA\\23.0.	Coder Import (b) (4)	24 Feb 2021 17:43:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Feb 2021 17:43:59
Data point term sent to Coder	System	24 Feb 2021 17:43:01
User entered 'Loose stool'	(b) (4), (b) (6)	24 Feb 2021 17:42:43

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:42:43

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:42:43

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:42:43

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User entered '29 Aug 2020'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:42:43

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:43

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:42:43

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User entered empty.	System	24 Feb 2021 17:42:43

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:42:43

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Folder: Adverse Events

Form: Adverse Events (3)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User entered '30 Aug 2020'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:42:43

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:43

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:42:43

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User entered empty.	System	24 Feb 2021 17:42:43

US3372184

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:43

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:42:43

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:42:43

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:43

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:42:43

US3372184

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:43

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:42:43

US3372184

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:42:43

US3372184

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:42:43

US3372184

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:43

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:42:43

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:42:43

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:42:43

US3372184

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:42:43

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:42:43

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Folder: Adverse Events

Form: Adverse Events (3)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:42:43

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:42:43

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:42:43

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:43

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:20:40
User closed query 'Per CDM: Action taken with investigational product is recorded as "Not Applicable" ,however, ae start date is between the two IP dose dates. Per CCGs p. 51, Action taken with investigational product is expected to be "Not Applicable" only when adverse event started after last of dose of IP or before first dose of investigational product. Kindly review and reconcile as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 14:08:46
Query 'Per CDM: Action taken with investigational product is recorded as "Not Applicable" ,however, ae start date is between the two IP dose dates. Per CCGs p. 51, Action taken with investigational product is expected to be "Not Applicable" only when adverse event started after last of dose of IP or before first dose of investigational product. Kindly review and reconcile as appropriate. ' answered with 'Data updated.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 21:17:51
Signature has been broken.	(b) (4), (b) (6)	05 Mar 2021 21:17:43
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 21:17:43
User opened query 'Per CDM: Action taken with investigational product is recorded as "Not Applicable" ,however, ae start date is between the two IP dose dates. Per CCGs p. 51, Action taken with investigational product is expected to be "Not Applicable" only when adverse event started after last of dose of IP or before first dose of investigational product. Kindly review and reconcile as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 04:07:12
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:42:43

US3372184

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:43

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User entered 'I'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:42:43

US3372184

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:42:43

US3372184

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:42:43

US3372184

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:43

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:42:43

US3372184

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:43

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:42:43

US3372184

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:43

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Mira Baron (b) (4)	24 Feb 2021 20:51:29
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 17:42:43

US3372184

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User entered '0'	System	24 Feb 2021 17:42:43

US3372184

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User entered '0'	System	24 Feb 2021 17:42:43

US3372184

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:14:43

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27

US3372184

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:43

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:21

US3372184

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:43

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:21
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	Coder Import (b) (4)	05 Apr 2021 15:45:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Apr 2021 15:45:44
Data point term sent to Coder	System	05 Apr 2021 15:33:11
User entered 'Nausea'	(b) (4), (b) (6)	05 Apr 2021 15:32:14

US3372184

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:43

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:21
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:32:14

US3372184

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:43

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:21
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:32:14

US3372184

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:43

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:21
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:32:14

US3372184

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:21
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
User entered '02 Sep 2020'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:32:14

US3372184

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:43

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:21
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:32:14

US3372184

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:43

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:21
User entered empty.	System	05 Apr 2021 15:32:14

US3372184

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:21
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:32:14

US3372184

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:43

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:21
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
User entered '05 Sep 2020'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:32:14

US3372184

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:43

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:21
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:32:14

US3372184

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:43

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:21
User entered empty.	System	05 Apr 2021 15:32:14

US3372184

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:43

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:21
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:32:14

US3372184

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:43

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:21
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:32:14

US3372184

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:43

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:21
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:32:14

US3372184

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:43

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:21
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:32:14

US3372184

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:21
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:32:14

US3372184

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:21
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:32:14

US3372184

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:43

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:21
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:32:14

US3372184

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:43

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:21
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:32:14

US3372184

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:21
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:32:14

US3372184

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:21
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:32:14

US3372184

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:21
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:32:14

US3372184

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:43

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:21
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:32:14

US3372184

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:43

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:21
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:32:14

US3372184

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:43

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:21
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:32:14

US3372184

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:43

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:21
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:32:14

US3372184

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:43

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:21
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:32:14

US3372184

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:43

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:21
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
User entered 'I'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:32:14

US3372184

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:43

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:21
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:32:14

US3372184

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:43

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:21
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:32:14

US3372184

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:43

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:21
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:32:14

US3372184

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:43

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:21
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:32:14

US3372184

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:43

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:21
User entered '0'	System	05 Apr 2021 15:32:14

US3372184

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:43

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:21
User entered 'I'	System	05 Apr 2021 15:32:14

US3372184

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:14:43

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:21

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:14:43

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:06:13
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 01:43:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 20:04:03
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:54:17

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:14:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:11:21
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: ESOMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 18:56:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 18:56:31
Data point term sent to Coder	System	14 Oct 2020 18:55:42
User entered 'esomeprazole'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:55:04

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:14:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:11:23
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:55:04

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:14:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:11:25
User entered 'gastroesophageal reflux disease'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:55:04

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:14:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:11:11
User entered '40'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:55:04

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:14:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:11:08
User entered 'mg (mg)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:55:04

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:14:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:11:28
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:55:04

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:14:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:11:30
User entered 'twice daily (BID)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:55:04

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:14:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:11:32
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:55:04

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:14:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:11:33
User entered 'Oral (ORAL)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:55:04

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:14:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:11:35
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:55:04

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:11:37
User entered 'un UNK 2012'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:55:04

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:14:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:11:39
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:55:04

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:14:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:11:41
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:55:04

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:14:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:11:43
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:55:04

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:14:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:11:46
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:55:04

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:14:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	14 Oct 2020 18:55:04

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 18:55:04

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Oct 2020 18:55:04

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:14:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 16:12:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: OTHER NERVOUS SYSTEM DRUGS, PRODUCT: PROPRANOLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 18:56:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	14 Oct 2020 18:55:43
User entered 'propranolol'	Peter Jacob (b) (4)	14 Oct 2020 18:55:30
	(b) (4)	

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:14:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:12:23
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:55:30

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:14:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:12:25
User entered 'essential tremors'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:55:30

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:14:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:12:27
User entered '10'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:55:30

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:14:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:12:28
User entered 'mg (mg)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:55:30

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:14:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:12:30
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:55:30

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:14:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:12:31
User entered 'once daily (QD)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:55:30

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:14:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:12:32
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:55:30

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:14:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:12:35
User entered 'Oral (ORAL)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:55:30

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:14:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:12:37
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:55:30

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:12:38
User entered 'un UNK 1999'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:55:30

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:14:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:12:40
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:55:30

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:14:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:12:41
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:55:30

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:14:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:12:42
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:55:30

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:14:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:12:44
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:55:30

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:14:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 18:55:30

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 18:55:30

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Oct 2020 18:55:30

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:14:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 16:13:11
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 04:19:22
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 04:19:22
	(b) (4)	
Data point term sent to Coder	System	14 Oct 2020 18:57:45
User entered 'tamsulosin'	Peter Jacob (b) (4)	14 Oct 2020 18:56:52
	(b) (4)	

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:14:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:13:13
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:56:52

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:14:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:13:14
User entered 'benign prostatic hyperplasia (BPH)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:56:52

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:14:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:13:16
User entered '0.4'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:56:52

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:14:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:13:17
User entered 'mg (mg)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:56:52

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:14:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:13:18
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:56:52

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:14:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:13:20
User entered 'once daily (QD)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:56:52

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:14:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:13:24
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:56:52

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:14:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:13:26
User entered 'Oral (ORAL)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:56:52

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:14:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:13:27
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:56:52

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:13:23
User entered 'un UNK 2019'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:56:52

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:14:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:13:28
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:56:52

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:14:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:13:30
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:56:52

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:14:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:13:31
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:56:52

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:14:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:13:34
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:56:52

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:14:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 18:56:52

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 18:56:52

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Oct 2020 18:56:52

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:14:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Oct 2020 16:13:54
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 18:58:37
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 18:58:37
	(b) (4)	
Data point term sent to Coder	System	14 Oct 2020 18:57:48
User entered 'tamsulosin'	Peter Jacob (b) (4)	14 Oct 2020 18:57:20
	(b) (4)	

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:14:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:13:55
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:57:20

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:14:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:13:56
User entered 'urinary retention'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:57:20

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:14:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:14:19
User entered '0.4'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:57:20

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:14:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:14:20
User entered 'mg (mg)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:57:20

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:14:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:14:22
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:57:20

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:14:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:14:23
User entered 'once daily (QD)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:57:20

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:14:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:14:25
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:57:20

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:14:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:14:26
User entered 'Oral (ORAL)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:57:20

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:14:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:14:28
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:57:20

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:14:30
User entered 'un UNK 2019'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:57:20

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:14:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:14:32
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:57:20

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:14:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:14:33
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:57:20

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:14:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:14:35
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:57:20

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:14:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 16:14:36
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:57:20

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:14:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 18:57:20

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 18:57:20

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Oct 2020 18:57:20

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:14:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:05:56
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 18:58:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 18:58:37
Data point term sent to Coder	System	14 Oct 2020 18:57:48
User entered 'losartan'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:57:44

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:14:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:05:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:57:44

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:14:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:06:00
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'hypertension'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:57:44

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:14:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:06:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 15:35:44
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'DOSE ADMINISTERED IS CORRECT AS RECORDED' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 18:57:11
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 08:41:23
User entered '20'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:57:44

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:14:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:06:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'mg (mg)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:57:44

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:14:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:06:06
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:57:44

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:14:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:06:08
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'once daily (QD)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:57:44

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:14:43

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:06:09
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:57:44

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:14:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:06:11
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'Oral (ORAL)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:57:44

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:14:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:06:12
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:57:44

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:06:16
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'un UNK 2017'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:57:44

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:14:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:06:17
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:57:44

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:14:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:06:19
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:57:44

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:14:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:06:21
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:57:44

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:14:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:06:23
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:57:44

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:14:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 18:57:44

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 18:57:44

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Oct 2020 18:57:44

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:14:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 20:06:36
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
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)	14 Oct 2020 18:59:39
User coded data point as Term Coded data point by	Coder Import (b) (4)	14 Oct 2020 18:59:39
User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	14 Oct 2020 18:58:49
User entered 'atorvastatin'	Peter Jacob (b) (4)	14 Oct 2020 18:58:11
	(b) (4)	

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:14:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:06:37
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:58:11

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:14:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:06:39
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'hypercholesterolemia'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:58:11

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:14:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:06:41
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered '20'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:58:11

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:14:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:06:42
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'mg (mg)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:58:11

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:14:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:06:44
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:58:11

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:14:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:06:45
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'every other day (QOD)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:58:11

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:14:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:06:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:58:11

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:14:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:06:50
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'Oral (ORAL)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:58:11

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:14:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:06:52
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:58:11

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:06:54
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'un UNK 2005'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:58:11

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:14:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:06:57
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:58:11

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:14:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:06:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:58:11

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:14:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:07:01
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:58:11

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:14:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:07:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:58:11

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:14:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 18:58:11

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	14 Oct 2020 18:58:11

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Oct 2020 18:58:11

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:14:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 20:07:17
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: ATENOLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 18:59:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 18:59:39
Data point term sent to Coder	System	14 Oct 2020 18:58:50
User entered 'atenolol'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:58:47

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:14:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:07:18
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:58:47

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:14:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:07:20
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'hypertension'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:58:47

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:14:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:07:21
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered '25'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:58:47

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:14:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:07:23
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'mg (mg)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:58:47

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:14:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:07:25
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:58:47

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:14:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:07:29
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'once daily (QD)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:58:47

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:14:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:07:30
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:58:47

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:14:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:07:31
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'Oral (ORAL)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:58:47

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:14:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:07:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:58:47

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:07:34
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'un UNK 1995'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:58:47

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:14:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:07:37
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:58:47

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:14:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:07:38
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:58:47

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:14:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:07:40
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:58:47

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:14:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:07:41
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:58:47

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:14:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 18:58:47

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 18:58:47

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Oct 2020 18:58:47

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:14:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:07:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: ALPRAZOLAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 19:00:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 19:00:42
Data point term sent to Coder	System	14 Oct 2020 18:59:51
User entered 'alprazolam'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:59:09

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:14:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:08:00
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:59:09

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:14:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:08:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'anxiety'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:59:09

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:14:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:08:03
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered '0.25'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:59:09

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:14:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:08:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'mg (mg)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:59:09

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:14:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:08:06
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:59:09

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:14:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:08:07
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'as needed (PRN)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:59:09

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:14:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:08:09
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:59:09

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:14:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:08:12
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'Oral (ORAL)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:59:09

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:14:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:08:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:59:09

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:08:15
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'un UNK 2010'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:59:09

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:14:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:08:16
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:59:09

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:14:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:08:18
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:59:09

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:14:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:08:21
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:59:09

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:14:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:08:20
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:59:09

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:14:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 18:59:09

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 18:59:09

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 18:59:09

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:14:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 20:08:40
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: AZELASTINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Nov 2020 23:13:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Nov 2020 23:13:37
Data point term sent to Coder	System	11 Nov 2020 18:58:39
Coding entries removed.	(b) (4), (b) (6)	11 Nov 2020 18:57:55
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: AZELASTINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 20:49:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 20:49:16
Data point term sent to Coder	System	14 Oct 2020 18:59:53
User entered 'azelastine'	Peter Jacob (b) (4)	14 Oct 2020 18:59:46

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:14:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:08:41
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:59:46

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:14:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:08:42
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'sinusitis'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:59:46

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:14:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:08:44
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered '0.1'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:59:46

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:14:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'mL (mL)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:59:46

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:14:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:08:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:59:46

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:14:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:08:48
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'once daily (QD)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:59:46

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:14:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:08:49
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:59:46

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:14:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:08:52
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 15:35:58
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' answered with 'ROUTE OF ADMINISTRATION HAS BEEN UPDATED AS RECORDED' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 18:58:34
User entered 'Nasal (NASAL)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Nov 2020 18:57:55
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 08:42:31
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:59:46

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:14:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:08:54
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:59:46

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:08:55
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'un UNK 1994'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:59:46

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:14:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:08:56
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:59:46

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:14:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:08:59
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:59:46

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:14:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:09:01
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:59:46

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:14:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:09:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:59:46

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:14:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 18:59:46

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 18:59:46

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Oct 2020 18:59:46

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:14:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 20:03:18
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:33
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:31
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: FAMCICLOVIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 19:01:43
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 19:01:43
	(b) (4)	
Data point term sent to Coder	System	14 Oct 2020 19:00:54
User entered 'famciclovir'	Peter Jacob (b) (4)	14 Oct 2020 19:00:17
	(b) (4)	

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:14:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:03:21
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:00:17

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:14:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:03:22
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'genital herpes'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:00:17

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:14:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:03:24
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered '500'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:00:17

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:14:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:03:29
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'mg (mg)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:00:17

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:14:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:03:30
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:00:17

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:14:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:03:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'as needed (PRN)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:00:17

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:14:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:03:34
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:00:17

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:14:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:03:35
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'Oral (ORAL)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:00:17

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:14:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:03:37
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:00:17

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:03:39
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'un UNK 2009'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:00:17

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:14:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:03:41
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:00:17

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:14:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:03:42
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:00:17

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:14:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:03:44
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:00:17

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:14:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:03:45
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:00:17

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:14:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 19:00:17

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 19:00:17

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 19:00:17

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:14:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 20:04:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS USED IN ERECTILE DYSFUNCTION, PRODUCT: SILDENAFIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 19:01:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 19:01:44
Data point term sent to Coder	System	14 Oct 2020 19:00:55
User entered 'sildenafil'	Peter Jacob (b) (4)	14 Oct 2020 19:00:53
	(b) (4)	

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:14:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:04:35
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:00:53

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:14:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:04:36
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'erectile dysfunction'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:00:53

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:14:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:04:37
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 15:36:10
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'DOSE OF ADMINISTRATION IS CORRECT AS RECORDED' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 19:01:01
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 08:43:09
User entered '35'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:00:53

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:14:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:04:16
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'mg (mg)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:00:53

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:14:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:04:18
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:00:53

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:14:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:04:20
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'as needed (PRN)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:00:53

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:14:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:04:23
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:00:53

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:14:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:04:28
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'Oral (ORAL)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:00:53

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:14:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:04:26
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:00:53

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:04:08
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'un UNK 1999'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:00:53

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:14:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:04:09
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:00:53

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:14:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:04:11
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:00:53

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:14:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:04:12
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:00:53

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:14:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:04:14
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:00:53

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:14:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 19:00:53

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 19:00:53

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 19:00:53

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:14:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 20:09:50
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 19:07:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 19:07:36
Data point term sent to Coder	System	14 Oct 2020 19:02:00
User entered 'celecoxib'	Peter Jacob (b) (4)	14 Oct 2020 19:01:40
	(b) (4)	

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:14:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:09:52
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:01:40

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:14:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:09:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'generalized osteoarthritis pain'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:01:40

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:14:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:09:54
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered '200'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:01:40

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:14:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:09:56
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'mg (mg)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:01:40

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:14:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:09:57
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:01:40

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:14:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:09:59
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'as needed (PRN)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:01:40

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:14:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:10:00
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:01:40

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:14:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:10:03
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'Oral (ORAL)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:01:40

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:14:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:10:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:01:40

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:10:06
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'un UNK 2002'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:01:40

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:14:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:10:07
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:01:40

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:14:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:10:08
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:01:40

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:14:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:10:10
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:01:40

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:14:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:10:11
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:01:40

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:14:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 19:01:40

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 19:01:40

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 19:01:40

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:14:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:10:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 22:37:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 22:37:28
Data point term sent to Coder	System	14 Oct 2020 19:03:01
User entered 'naproxen'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:02:21

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:14:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:10:35
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:02:21

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:14:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:10:39
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'generalized osteoarthritis pain'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:02:21

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:14:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:10:42
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered '550'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:02:21

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:14:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:10:44
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'mg (mg)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:02:21

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:14:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:10:46
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:02:21

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:14:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 20:10:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'as needed (PRN)'	Peter Jacob (b) (4)	14 Oct 2020 19:02:21
	(b) (4)	

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:14:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:10:50
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:02:21

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:14:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 20:10:51
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'Oral (ORAL)'	Peter Jacob (b) (4)	14 Oct 2020 19:02:21
	(b) (4)	

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:14:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:10:52
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:02:21

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:10:54
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'un UNK 1995'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:02:21

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:14:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:10:55
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:02:21

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:14:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:10:56
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:02:21

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:14:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:11:01
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:02:21

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:14:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:10:59
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:02:21

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:14:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 19:02:21

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 19:02:21

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 19:02:21

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:14:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:11:15
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
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) (b) (4)	14 Oct 2020 19:34:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 19:34:32
Data point term sent to Coder	System	14 Oct 2020 19:04:03
User entered 'docusate'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:03:07

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:14:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:11:16
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:03:07

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:14:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:11:18
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'constipation prophylaxis/prevention'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:03:07

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:14:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:11:19
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered '100'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:03:07

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:14:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:11:21
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'mg (mg)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:03:07

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:14:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:11:22
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:03:07

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:14:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:11:24
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'once daily (QD)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:03:07

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:14:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:11:27
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:03:07

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:14:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:11:29
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'Oral (ORAL)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:03:07

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:14:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:11:31
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:03:07

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:11:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'un UNK 2018'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:03:07

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:14:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:11:34
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:03:07

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:14:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:11:35
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:03:07

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:14:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:11:37
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:03:07

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:14:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:11:39
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:03:07

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:14:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 19:03:07

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 19:03:07

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Oct 2020 19:03:07

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:14:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:11:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL 3350, PRODUCTSYNONYM: MIRALAX - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 19:04:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 19:04:40
Data point term sent to Coder	System	14 Oct 2020 19:04:05
User entered 'miralax'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:04:00

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:14:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:11:54
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:04:00

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:14:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:11:56
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'constipation prophylaxis/prevention'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:04:00

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:14:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:11:57
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered '8500'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:04:00

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:14:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:11:59
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'mg (mg)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:04:00

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:14:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:12:00
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:04:00

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:14:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:12:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'once daily (QD)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:04:00

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:14:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:12:05
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:04:00

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:14:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:12:06
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'Oral (ORAL)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:04:00

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:14:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:12:07
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:04:00

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:12:09
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'un UNK 2018'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:04:00

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:14:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:12:10
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:04:00

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:14:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:12:12
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:04:00

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:14:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:12:16
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:04:00

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:14:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:12:14
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:04:00

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:14:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 19:04:00

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 19:04:00

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Oct 2020 19:04:00

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:14:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 20:12:29
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Oct 2020 19:06:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Oct 2020 19:06:10
Data point term sent to Coder	System	14 Oct 2020 19:05:11
User entered 'multi-vitamins'	Peter Jacob (b) (4)	14 Oct 2020 19:04:34
	(b) (4)	

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:14:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:12:31
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User closed query 'Per DM CLR: Prophylaxis = NO, however, the recorded medication is either a vaccine, vitamin/supplement, contraceptive or given as prophylaxis/prevention of a disease. Please confirm and update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 15:36:33
Query 'Per DM CLR: Prophylaxis = NO, however, the recorded medication is either a vaccine, vitamin/supplement, contraceptive or given as prophylaxis/prevention of a disease. Please confirm and update as appropriate, otherwise clarify. ' answered with 'MULTI-VITAMINS ARE RECOGNIZED AS DIETARY SUPPLEMENT AS RECORDED' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 19:19:45
User opened query 'Per DM CLR: Prophylaxis = NO, however, the recorded medication is either a vaccine, vitamin/supplement, contraceptive or given as prophylaxis/prevention of a disease. Please confirm and update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 08:44:26
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:04:34

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:14:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:12:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'dietary supplement'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:04:34

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:14:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:12:34
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'I'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:04:34

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:14:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:12:37
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'tablet (TABLET)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:04:34

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:14:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:12:39
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:04:34

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:14:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:12:40
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'once daily (QD)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:04:34

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:14:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:12:42
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:04:34

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:14:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:12:44
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'Oral (ORAL)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:04:34

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:14:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:12:45
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:04:34

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:12:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'un UNK 1975'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:04:34

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:14:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:12:50
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:04:34

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:14:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:12:51
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:04:34

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:14:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:12:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:04:34

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:14:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:12:54
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:04:34

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:14:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 19:04:34

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 19:04:34

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Oct 2020 19:04:34

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:14:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:13:06
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 19:06:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 19:06:34
Data point term sent to Coder	System	14 Oct 2020 19:06:13
User entered 'vitamin D3'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:05:15

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:14:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:13:08
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User closed query 'Per DM CLR: Prophylaxis = NO, however, the recorded medication is either a vaccine, vitamin/supplement, contraceptive or given as prophylaxis/prevention of a disease. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 15:36:37
Query 'Per DM CLR: Prophylaxis = NO, however, the recorded medication is either a vaccine, vitamin/supplement, contraceptive or given as prophylaxis/prevention of a disease. Please confirm and update as appropriate, otherwise clarify.' answered with 'VITAMIN D3 IS RECOGNIZED AS A DIETARY SUPPLEMENT AS RECORDED' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 19:20:46
User opened query 'Per DM CLR: Prophylaxis = NO, however, the recorded medication is either a vaccine, vitamin/supplement, contraceptive or given as prophylaxis/prevention of a disease. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 08:44:59
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:05:15

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:14:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:13:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'dietary supplement'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:05:15

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:14:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:13:15
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered '2000'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:05:15

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:14:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:13:16
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 15:36:40
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'DOSE UNIT IS CORRECT AS RECORDED' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 19:22:11
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 08:45:12
User entered 'mg (mg)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:05:15

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:14:43

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:13:18
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:05:15

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:14:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:13:19
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'once daily (QD)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:05:15

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:14:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:13:23
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:05:15

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:14:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:13:25
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'Oral (ORAL)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:05:15

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:14:43

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:13:26
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:05:15

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:13:28
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'un UNK 2009'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:05:15

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:14:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:13:30
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:05:15

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:14:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:13:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:05:15

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:14:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:13:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:05:15

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:14:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:13:36
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:05:15

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:14:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 19:05:15

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 19:05:15

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Oct 2020 19:05:15

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:14:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 20:13:51
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Oct 2020 19:08:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Oct 2020 19:08:42
Data point term sent to Coder	System	14 Oct 2020 19:07:14
User entered 'calcium'	Peter Jacob (b) (4)	14 Oct 2020 19:06:23
	(b) (4)	

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:14:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:13:52
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User closed query 'Per DM CLR: Prophylaxis = NO, however, the recorded medication is either a vaccine, vitamin/supplement, contraceptive or given as prophylaxis/prevention of a disease. Please confirm and update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 15:36:51
Query 'Per DM CLR: Prophylaxis = NO, however, the recorded medication is either a vaccine, vitamin/supplement, contraceptive or given as prophylaxis/prevention of a disease. Please confirm and update as appropriate, otherwise clarify. ' answered with 'CALCIUM IS RECOGNIZED AS AN DIETARY SUPPLEMENT AS RECORDED' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 19:23:03
User opened query 'Per DM CLR: Prophylaxis = NO, however, the recorded medication is either a vaccine, vitamin/supplement, contraceptive or given as prophylaxis/prevention of a disease. Please confirm and update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 08:45:50
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:06:23

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:14:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:13:54
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'dietary supplement'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:06:23

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:14:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:13:55
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered '2000'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:06:23

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:14:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:13:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'mg (mg)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:06:23

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:14:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:14:00
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:06:23

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:14:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:14:01
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'once daily (QD)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:06:23

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:14:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:14:03
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:06:23

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:14:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:14:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'Oral (ORAL)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:06:23

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:14:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:14:06
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:06:23

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:14:07
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'un UNK 2009'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:06:23

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:14:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:14:09
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:06:23

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:14:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:14:28
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:06:23

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:14:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:14:30
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:06:23

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:14:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:14:31
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:06:23

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:14:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 19:06:23

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 19:06:23

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Oct 2020 19:06:23

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:14:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:36
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PERTUSSIS VACCINES, PRODUCT: DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE;TETANUS VACCINE TOXOID, PRODUCTSYNONYM: DIPHTHERIA TETANUS PERTUSSIS VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 14:37:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 14:37:33
User signature succeeded.	Mira Baron (b) (4) (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 20:15:00
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PERTUSSIS VACCINES, PRODUCT: DIPHTHERIA VACCINE;PERTUSSIS VACCINE;TETANUS VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 19:09:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 19:09:30
Data point term sent to Coder	System	14 Oct 2020 19:08:19
User entered 'diphtheria tetanus and acellular pertussis vaccine'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:08:09

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:14:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:36
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:15:03
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:08:09

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:14:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:36
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:15:12
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:15:10
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 20:15:09
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'diphtheria tetanus and acellular pertussis prophylaxis/prevention'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:08:09

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:14:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:36
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:15:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered '0.5'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:08:09

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:14:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:36
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:15:15
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'mL (mL)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:08:09

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:14:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:36
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:15:16
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:08:09

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:14:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:36
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:15:20
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'once (ONCE)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:08:09

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:14:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:36
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:15:21
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:08:09

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:14:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:36
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:15:23
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'Intramuscular (INTRAMUSCULAR)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:08:09

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:14:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:36
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:15:25
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:08:09

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:36
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:15:27
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'un UNK 2011'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:08:09

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:14:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:36
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:15:29
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:08:09

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:14:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:36
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:15:30
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:08:09

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:14:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:36
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:15:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'un UNK 2011'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:08:09

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:14:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:36
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:15:34
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:08:09

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:14:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:36
User entered empty.	System	14 Oct 2020 19:08:09

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:36
User entered empty.	System	14 Oct 2020 19:08:09

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:36
User entered empty.	System	14 Oct 2020 19:08:09

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:14:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:53
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:15:49
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PNEUMOCOCCAL VACCINES, PRODUCT: PNEUMOCOCCAL VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 19:10:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 19:10:34
Data point term sent to Coder	System	14 Oct 2020 19:09:21
User entered 'pneumonia vaccine'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:08:41

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:14:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:53
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:08:41

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:14:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:53
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:15:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'pneumonia prophylaxis/prevention'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:08:41

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:14:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:53
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:15:54
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered '0.5'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:08:41

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:14:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:53
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'mL (mL)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:08:41

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:14:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:53
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:08:41

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:14:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:53
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:15:59
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'once (ONCE)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:08:41

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:14:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:53
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:16:02
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:08:41

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:14:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:53
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:16:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'Intramuscular (INTRAMUSCULAR)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:08:41

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:14:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:53
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:16:05
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:08:41

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:53
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:16:07
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'un UNK 2015'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:08:41

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:14:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:53
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:16:08
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:08:41

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:14:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:53
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:16:10
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:08:41

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:14:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:53
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:16:12
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'un UNK 2015'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:08:41

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:14:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:53
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:16:15
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:08:41

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:14:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:53
User entered empty.	System	14 Oct 2020 19:08:41

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:53
User entered empty.	System	14 Oct 2020 19:08:41

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:53
User entered empty.	System	14 Oct 2020 19:08:41

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:14:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:48
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:16:26
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: VARICELLA ZOSTER VACCINES, PRODUCT: VARICELLA ZOSTER VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 19:10:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 19:10:34
Data point term sent to Coder	System	14 Oct 2020 19:09:21
User entered 'herpes zoster vaccine'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:09:04

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:14:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:48
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:16:28
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:09:04

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:14:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:48
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:16:30
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'herpes zoster prophylaxis/prevention'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:09:04

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:14:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:48
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:16:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered '0.5'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:09:04

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:14:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:48
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:16:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'mL (mL)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:09:04

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:14:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:48
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:16:35
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:09:04

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:14:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:48
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:16:37
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'once (ONCE)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:09:04

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:14:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:48
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:16:40
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:09:04

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:14:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:48
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:16:41
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'Intramuscular (INTRAMUSCULAR)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:09:04

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:14:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:48
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:16:43
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:09:04

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:48
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:16:44
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'un Sep 2019'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:09:04

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:14:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:48
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:16:46
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:09:04

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:14:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:48
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:16:47
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:09:04

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:14:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:48
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:16:49
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'un Sep 2019'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:09:04

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:14:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:48
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:16:51
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:09:04

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:14:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:48
User entered empty.	System	14 Oct 2020 19:09:04

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:48
User entered empty.	System	14 Oct 2020 19:09:04

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:48
User entered empty.	System	14 Oct 2020 19:09:04

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:14:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:43
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:17:05
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 19:11:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 19:11:29
Data point term sent to Coder	System	14 Oct 2020 19:10:22
User entered 'influenza vaccine'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:09:39

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:14:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:43
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:17:07
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:09:39

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:14:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:43
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:17:09
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'influenza prophylaxis/prevention'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:09:39

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:14:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:43
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:17:10
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered '0.5'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:09:39

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:14:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:43
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:17:12
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'mL (mL)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:09:39

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:14:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:43
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:17:14
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:09:39

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:14:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:43
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:17:16
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'once (ONCE)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:09:39

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:14:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:43
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:17:19
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:09:39

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:14:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:43
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:17:20
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'Intramuscular (INTRAMUSCULAR)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:09:39

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:14:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:43
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:17:21
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:09:39

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:43
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:17:26
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'un Sep 2019'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:09:39

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:14:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:43
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:17:27
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:09:39

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:14:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:43
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:17:29
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:09:39

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:14:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:43
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:17:30
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'un Sep 2019'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:09:39

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:14:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:43
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:17:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:09:39

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:14:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:43
User entered empty.	System	14 Oct 2020 19:09:39

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:43
User entered empty.	System	14 Oct 2020 19:09:39

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:57:43
User entered empty.	System	14 Oct 2020 19:09:39

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:14:43

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
User closed query 'Per DM CLR: Please review medication name to record the specific Corticosteroid given (e.g. Dexamethasone, Prednisone, etc.), please record the generic/trade name if known. Update as appropriate, otherwise clarify.' (Site from DM). DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	29 Nov 2020 03:20:13
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:17:53
Query 'Per DM CLR: Please review medication name to record the specific Corticosteroid given (e.g. Dexamethasone, Prednisone, etc.), please record the generic/trade name if known. Update as appropriate, otherwise clarify.' answered with 'CORTICOSTEROID INJECTION IS A FORM OF STEROID AS RECORDED' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User opened query 'Per DM CLR: Please review medication name to record the specific Corticosteroid given (e.g. Dexamethasone, Prednisone, etc.), please record the generic/trade name if known. Update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 19:26:54
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PRODUCT: CORTICOSTEROID NOS - version WHODrug-Global-B3\202003.	(b) (4), (b) (6)	11 Nov 2020 08:46:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 05:27:30
Data point term sent to Coder	System	15 Oct 2020 05:27:30
User entered 'corticosteroid injection'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:10:23 14 Oct 2020 19:10:23

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:14:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:17:55
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:10:23

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:14:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:17:56
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'carpal tunnel syndrome left wrist'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:10:23

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:14:43

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MG, etc) instead of volume (mL), as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Nov 2020 03:20:15
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 20:17:58
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MG, etc) instead of volume (mL), as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'DOSE OF ADMINISTRATION IS CORRECT AS RECORDED' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 19:28:40
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MG, etc) instead of volume (mL), as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 08:47:00
User entered '5'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:10:23

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:14:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:18:01
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'mL (mL)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:10:23

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:14:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:18:03
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:10:23

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:14:43

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:18:04
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'once (ONCE)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:10:23

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:14:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:18:06
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:10:23

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:14:43

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:18:08
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'Intramuscular (INTRAMUSCULAR)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:10:23

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:14:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:18:09
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:10:23

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:18:11
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'un Oct 2019'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:10:23

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:14:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:18:15
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:10:23

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:14:43

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:18:16
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:10:23

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:14:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:18:18
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'un Oct 2019'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:10:23

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:14:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:18:19
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:10:23

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:14:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 19:10:23

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 19:10:23

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 19:10:23

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:14:43

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:54:10
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:19:15
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 20:19:03
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 19:12:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 19:12:31
Data point term sent to Coder	System	14 Oct 2020 19:11:24
User entered 'acetaminophen'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:11:02

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:14:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:54:10
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:11:02

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:14:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:54:10
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
User closed query 'Per CDM: Requery: Please consider to update AE form for this indication within the same time frame as no AE has been recorded. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:04:44
Query 'Per CDM: Requery: Please consider to update AE form for this indication within the same time frame as no AE has been recorded. Thank you.' answered with 'AE added' (Site from DM).	Mary Sergalis (b) (4)	16 Nov 2020 19:51:39
User opened query 'Per CDM: Requery: Please consider to update AE form for this indication within the same time frame as no AE has been recorded. Thank you.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 06:34:38
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 06:24:22
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'RIGHT LOWER ABDOMINAL PAIN IS RECOGNIZED AS AN SOLICITED EVENT AS RECORDED' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 19:29:18
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 08:48:55
User entered 'right lower abdominal pain'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:11:02

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:14:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:54:10
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered '500'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:11:02

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:14:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:54:10
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'mg (mg)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:11:02

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:14:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:54:10
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:11:02

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:14:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:54:10
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'once (ONCE)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:11:02

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:14:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:54:10
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:11:02

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:14:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:54:10
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'Oral (ORAL)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:11:02

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:14:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:54:10
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:11:02

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:54:10
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered '28 Aug 2020'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:11:02

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:14:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:54:10
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:11:02

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:14:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:54:10
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:11:02

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:14:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:54:10
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered '28 Aug 2020'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:11:02

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:14:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:54:10
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:54:08
User closed query 'Per CDM: Requery: Response noted, however please consider to update the field as NO as this is not an solicited event as per protocol or else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 15:04:52
Query 'Per CDM: Requery: Response noted, however please consider to update the field as NO as this is not an solicited event as per protocol or else clarify. Thank you.' answered with 'updated' (Site from DM).	Mary Sergalis (b) (4)	16 Nov 2020 19:52:12
DataPoint Un-verified.	Mary Sergalis (b) (4)	16 Nov 2020 19:52:05
User entered 'No (N)' reason for change: Data Entry Error	Mary Sergalis (b) (4)	16 Nov 2020 19:52:05
User opened query 'Per CDM: Requery: Response noted, however please consider to update the field as NO as this is not an solicited event as per protocol or else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 06:21:06
User closed query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 06:21:06
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
Query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' answered with 'RIGHT LOWER ABDOMINAL PAIN IS RECOGNIZED AS AN SOLICITED EVENT AS RECORDED' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 19:30:59

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:14:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 08:51:00
User entered 'Yes (Y)'	Peter Jacob (b) (4)	14 Oct 2020 19:11:02

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:14:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:54:10
User entered empty.	System	14 Oct 2020 19:11:02

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:54:10
User entered empty.	System	14 Oct 2020 19:11:02

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:54:10
User entered empty.	System	14 Oct 2020 19:11:02

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:14:43

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:54:06
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANIC ACID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Dec 2020 17:27:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Dec 2020 17:27:42
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:36:21
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN TRIHYDRATE;CLAVULANATE POTASSIUM, PRODUCTSYNONYM: AMOXICILLIN/CLAVULANIC ACID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 19:13:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Oct 2020 19:13:34
Data point term sent to Coder	System	14 Oct 2020 19:12:28
User entered 'amoxicillin/clavulanic acid'	Peter Jacob (b) (4)	14 Oct 2020 19:12:16

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:14:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:54:06
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:36:19
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:12:16

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:14:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:54:06
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:36:22
User entered 'post surgical infection prevention'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:12:16

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:14:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:54:06
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:36:24
User entered '875/125'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:12:16

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:14:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:54:06
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:36:26
User entered 'mg (mg)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:12:16

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:14:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:54:06
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:36:29
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:12:16

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:14:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:54:06
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:36:30
User entered 'twice daily (BID)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:12:16

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:14:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:54:06
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:36:32
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:12:16

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:14:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:54:06
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:36:33
User entered 'Oral (ORAL)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:12:16

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:14:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:54:06
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:36:35
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:12:16

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:54:06
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:36:38
User entered '07 Sep 2020'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:12:16

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:14:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:54:06
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:36:39
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:12:16

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:14:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:54:06
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:36:41
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:12:16

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:14:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:54:06
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:36:43
User entered '10 Sep 2020'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:12:16

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:14:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:54:06
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:36:45
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:12:16

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:14:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:54:06
User entered '2'	System	14 Oct 2020 19:12:16

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:54:06
User entered '1'	System	14 Oct 2020 19:12:16

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:54:06
User entered '804 (804)'	System	14 Oct 2020 19:12:16

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:14:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:55
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:40:53
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN;TAZOBACTAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 04:50:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 04:50:24
Data point term sent to Coder	System	14 Oct 2020 19:13:30
User entered 'piperacillin-tazobactam'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:13:07

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:14:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:55
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:40:56
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:13:07

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:14:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:55
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:41:03
User entered 'appendicitis'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:13:07

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:14:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:55
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:41:05
User entered '3375'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:13:07

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:14:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:55
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:41:06
User entered 'mg (mg)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:13:07

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:14:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:55
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:42:31
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:13:07

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:14:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:55
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:40:36
User closed query 'Please verify, noted in medical records as every 8 hours.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:40:34
User entered 'three times daily (TID)' reason for change: Data Entry Error	Mary Sergalis (b) (4)	10 Nov 2020 17:28:21
Query 'Please verify, noted in medical records as every 8 hours.' answered with 'FREQUENCY IS PRN (AS NEEDED) AS RECORDED ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:18:19
User opened query 'Please verify, noted in medical records as every 8 hours.' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 16:42:30
User entered 'as needed (PRN)'	Peter Jacob (b) (4)	14 Oct 2020 19:13:07

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:14:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:55
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:42:35
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:13:07

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:14:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:55
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:41:11
User entered 'Intravenous (INTRAVENOUS)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:13:07

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:14:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:55
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:42:38
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:13:07

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:55
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:41:17
User entered '02 Sep 2020'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:13:07

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:14:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:55
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:42:39
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:13:07

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:14:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:55
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:41:20
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:13:07

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:14:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:55
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:41:31
User entered '03 Sep 2020'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:13:07

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:14:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:55
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
User closed query 'The medications were not added to this subject in Rave as noted. Please add: lactated ringer's, hydralazine10 mg q4 prn, morphine injectable 4 mg prn, oxycodone 1-2 tab po q4 prn, pantoprazole 40 mg IV qd, Zofran 2ml IV push q6 hr prn.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:43:32
Query 'The medications were not added to this subject in Rave as noted. Please add: lactated ringer's, hydralazine10 mg q4 prn, morphine injectable 4 mg prn, oxycodone 1-2 tab po q4 prn, pantoprazole 40 mg IV qd, Zofran 2ml IV push q6 hr prn.' answered with 'entered' (Site from CRA).	Mary Sergalis (b) (4)	18 Nov 2020 17:11:57
User opened query 'The medications were not added to this subject in Rave as noted. Please add: lactated ringer's, hydralazine10 mg q4 prn, morphine injectable 4 mg prn, oxycodone 1-2 tab po q4 prn, pantoprazole 40 mg IV qd, Zofran 2ml IV push q6 hr prn.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 17:40:22
User closed query 'Please add to the CRF.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 21:49:02
Query 'Please add to the CRF.' answered with 'This is in the CRF. Frequency updated in both' (Site from CRA).	Mary Sergalis (b) (4)	10 Nov 2020 17:28:47
User opened query 'Please add to the CRF.' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 16:09:46
User closed query 'Please verify if the following medications noted in the hospital records in source should be added: lactated ringer's, hydralazine10 mg q4 prn, morphine injectable 4 mg prn, oxycodone 1-2 tab po q4 prn, pantoprazole 40 mg IV qd, Zofran 2ml IV push q6 hr prn.' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 16:09:46
Query 'Please verify if the following medications noted in the hospital records in source should be added: lactated ringer's, hydralazine10 mg q4 prn, morphine injectable 4 mg prn, oxycodone 1-2 tab po q4 prn, pantoprazole 40 mg IV qd, Zofran 2ml IV push q6 hr prn.' answered with 'MEDICATION HAS BEEN UPDATED IN AE' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:19:17

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:14:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User opened query 'Please verify if the following medications noted in the hospital records in source should be added: lactated ringer's, hydralazine10 mg q4 prn, morphine injectable 4 mg prn, oxycodone 1-2 tab po q4 prn, pantoprazole 40 mg IV qd, Zofran 2ml IV push q6 hr prn.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:47:23
	(b) (4), (b) (6)	27 Oct 2020 16:41:37
User entered 'No (N)'	Peter Jacob (b) (4)	14 Oct 2020 19:13:07
	(b) (4)	

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:14:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:55
User entered '3'	System	10 Nov 2020 17:28:21
User entered empty.	System	14 Oct 2020 19:13:07

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:55
User entered '1'	System	10 Nov 2020 17:28:21
User entered empty.	System	14 Oct 2020 19:13:07

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:55
User entered '804 (804)'	System	10 Nov 2020 17:28:21
User entered empty.	System	14 Oct 2020 19:13:07

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:14:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:47
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Nov 2020 21:11:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Nov 2020 21:11:52
Data point term sent to Coder	System	17 Nov 2020 20:55:41
User entered 'Influenza Vaccine'	Elena Acosta (b) (4)	17 Nov 2020 20:55:29

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:14:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:47
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
User entered 'Yes (Y)'	(b) (4) Elena Acosta (b) (4) (b) (4)	17 Nov 2020 20:55:29

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:14:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:47
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
User entered 'Influenza Prevention'	(b) (4) Elena Acosta (b) (4) (b) (4)	17 Nov 2020 20:55:29

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:14:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:47
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
User entered '0.5'	(b) (4) Elena Acosta (b) (4) (b) (4)	17 Nov 2020 20:55:29

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:14:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:47
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
User entered 'mL (mL)'	(b) (4) Elena Acosta (b) (4) (b) (4)	17 Nov 2020 20:55:29

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:14:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:47
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
User entered empty.	(b) (4) Elena Acosta (b) (4) (b) (4)	17 Nov 2020 20:55:29

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:14:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:47
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
User entered 'once (ONCE)'	(b) (4) Elena Acosta (b) (4) (b) (4)	17 Nov 2020 20:55:29

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:14:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:47
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
User entered empty.	(b) (4) Elena Acosta (b) (4) (b) (4)	17 Nov 2020 20:55:29

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:14:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:47
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Elena Acosta (b) (4)	17 Nov 2020 20:55:29

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:14:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:47
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
User entered empty.	(b) (4) Elena Acosta (b) (4) (b) (4)	17 Nov 2020 20:55:29

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:47
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
User entered '14 Oct 2020'	(b) (4) Elena Acosta (b) (4) (b) (4)	17 Nov 2020 20:55:29

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:14:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:47
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
User entered '0'	(b) (4) Elena Acosta (b) (4)	17 Nov 2020 20:55:29

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:14:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:47
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
User entered 'No (N)'	(b) (4) Elena Acosta (b) (4) (b) (4)	17 Nov 2020 20:55:29

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:14:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:47
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
User entered '14 Oct 2020'	(b) (4) Elena Acosta (b) (4) (b) (4)	17 Nov 2020 20:55:29

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:14:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:47
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
User entered 'No (N)'	(b) (4) Elena Acosta (b) (4)	17 Nov 2020 20:55:29

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:14:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:47
User entered empty.	System	17 Nov 2020 20:55:29

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:47
User entered empty.	System	17 Nov 2020 20:55:29

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:47
User entered empty.	System	17 Nov 2020 20:55:29

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:14:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:29
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:43:46
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON, ATC: HYDRAZINOPHTHALAZINE DERIVATIVES, PRODUCT: HYDRALAZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 04:11:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 04:11:02
Data point term sent to Coder	System	18 Nov 2020 17:14:09
User entered 'Hydralazine'	Mary Sergalis (b) (4) 	18 Nov 2020 17:13:48

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:14:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:29
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:28:44
User entered 'No (N)'	Mary Sergalis (b) (4)	18 Nov 2020 17:13:48

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:14:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:29
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:28:46
User entered 'Hypertension'	Mary Sergalis (b) (4)	18 Nov 2020 17:13:48

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:14:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:29
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:28:47
User entered '10'	Mary Sergalis (b) (4)	18 Nov 2020 17:13:48

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:14:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:29
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:28:49
User entered 'mg (mg)'	Mary Sergalis (b) (4)	18 Nov 2020 17:13:48

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:14:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:29
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:28:50
User entered empty.	Mary Sergalis (b) (4)	18 Nov 2020 17:13:48

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:14:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:29
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:28:52
User entered 'as needed (PRN)'	Mary Sergalis (b) (4)	18 Nov 2020 17:13:48

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:14:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:29
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:28:54
User entered empty.	Mary Sergalis (b) (4)	18 Nov 2020 17:13:48

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:14:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:29
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:28:57
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	Mary Sergalis (b) (4)	18 Nov 2020 17:13:48

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:14:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:29
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:28:58
User entered empty.	Mary Sergalis (b) (4)	18 Nov 2020 17:13:48

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:14:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:29
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:29:00
User entered '02 Sep 2020'	Mary Sergalis (b) (4)	18 Nov 2020 17:13:48

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:14:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:29
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:29:01
User entered '0'	Mary Sergalis (b) (4)	18 Nov 2020 17:13:48

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:14:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:29
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:29:03
User entered 'No (N)'	Mary Sergalis (b) (4)	18 Nov 2020 17:13:48

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:14:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:29
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:29:04
User entered '05 Sep 2020'	Mary Sergalis (b) (4)	18 Nov 2020 17:13:48

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:14:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:29
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:29:06
User entered 'No (N)'	Mary Sergalis (b) (4)	18 Nov 2020 17:13:48

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:14:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:29
User entered empty.	System	18 Nov 2020 17:13:48

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:29
User entered empty.	System	18 Nov 2020 17:13:48

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:29
User entered empty.	System	18 Nov 2020 17:13:48

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:14:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:24
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:43:56
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: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 17:37:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Nov 2020 17:37:47
Data point term sent to Coder	System	18 Nov 2020 17:36:37
User entered 'Lactated Ringers'	Mary Sergalis (b) (4)	18 Nov 2020 17:35:44

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:14:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:24
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:14:56
User entered 'No (N)'	Mary Sergalis (b) (4)	18 Nov 2020 17:35:44

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:14:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:24
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
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. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Jan 2021 09:21:23
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'data correct as is' (Site from DM).	Peter Jacob (b) (4) (b) (4)	19 Jan 2021 20:41:18
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. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 09:09:12
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:14:58
User entered 'Keep Vein open for IV medications'	Mary Sergalis (b) (4)	18 Nov 2020 17:35:44

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:14:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:24
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:15:00
User entered '1000'	Mary Sergalis (b) (4)	18 Nov 2020 17:35:44

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:14:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:24
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:15:02
User entered 'mL (mL)'	Mary Sergalis (b) (4)	18 Nov 2020 17:35:44

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:14:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:24
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:15:04
User entered empty.	Mary Sergalis (b) (4)	18 Nov 2020 17:35:44

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:14:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:24
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:15:05
User entered 'once daily (QD)'	Mary Sergalis (b) (4)	18 Nov 2020 17:35:44

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:14:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:24
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:15:07
User entered empty.	Mary Sergalis (b) (4)	18 Nov 2020 17:35:44

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:14:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:24
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:14:49
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Mary Sergalis (b) (4)	18 Nov 2020 17:35:44

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:14:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:24
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:15:09
User entered empty.	Mary Sergalis (b) (4)	18 Nov 2020 17:35:44

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:14:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:24
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4)	
	Peter Jacob (b) (4)	19 Jan 2021 20:42:05
	(b) (4)	
User entered '02 Sep 2020' reason for change: Data Entry Error	Peter Jacob (b) (4)	19 Jan 2021 20:42:05
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 15:14:52
User entered '2 Sep 2020'	Mary Sergalis (b) (4)	18 Nov 2020 17:35:44

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:14:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:24
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:15:11
User entered '0'	Mary Sergalis (b) (4)	18 Nov 2020 17:35:44

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:14:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:24
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:15:13
User entered 'No (N)'	Mary Sergalis (b) (4)	18 Nov 2020 17:35:44

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:14:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:24
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4)	
	Peter Jacob (b) (4)	19 Jan 2021 20:42:05
	(b) (4)	
User entered '05 Sep 2020' reason for change: Data Entry Error	Peter Jacob (b) (4)	19 Jan 2021 20:42:05
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:20:51
User entered '5 Sep 2020'	Mary Sergalis (b) (4)	18 Nov 2020 17:35:44

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:14:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:24
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:15:17
User entered 'No (N)'	Mary Sergalis (b) (4)	18 Nov 2020 17:35:44

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:14:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:24
User entered '1'	System	18 Nov 2020 17:35:44

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:24
User entered '1'	System	18 Nov 2020 17:35:44

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:24
User entered '804 (804)'	System	18 Nov 2020 17:35:44

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:14:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:19
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:44:07
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) (b) (4)	19 Nov 2020 03:51:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 03:51:59
Data point term sent to Coder	System	18 Nov 2020 17:37:37
User entered 'Morphine'	Mary Sergalis (b) (4) 	18 Nov 2020 17:36:56

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:14:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:19
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:23:15
User entered 'No (N)'	Mary Sergalis (b) (4)	18 Nov 2020 17:36:56

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:14:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:19
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:23:18
User entered 'Right Lower Abdominal Pain'	Mary Sergalis (b) (4)	18 Nov 2020 17:36:56

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:14:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:19
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:23:19
User entered '4'	Mary Sergalis (b) (4)	18 Nov 2020 17:36:56

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:14:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:19
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:23:21
User entered 'mg (mg)'	Mary Sergalis (b) (4)	18 Nov 2020 17:36:56

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:14:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:19
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:23:22
User entered empty.	Mary Sergalis (b) (4)	18 Nov 2020 17:36:56

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:14:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:19
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:23:24
User entered 'as needed (PRN)'	Mary Sergalis (b) (4)	18 Nov 2020 17:36:56

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:14:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:19
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:23:26
User entered empty.	Mary Sergalis (b) (4)	18 Nov 2020 17:36:56

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:14:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:19
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:23:28
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	Mary Sergalis (b) (4)	18 Nov 2020 17:36:56

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:14:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:19
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:23:29
User entered empty.	Mary Sergalis (b) (4)	18 Nov 2020 17:36:56

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:14:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:19
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4)	
	Peter Jacob (b) (4)	19 Jan 2021 20:42:42
	(b) (4)	
User entered '02 Sep 2020' reason for change: Data Entry Error	Peter Jacob (b) (4)	19 Jan 2021 20:42:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 15:23:31
User entered '2 Sep 2020'	Mary Sergalis (b) (4)	18 Nov 2020 17:36:56

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:14:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:19
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:23:33
User entered '0'	Mary Sergalis (b) (4)	18 Nov 2020 17:36:56

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:14:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:19
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:23:35
User entered 'No (N)'	Mary Sergalis (b) (4)	18 Nov 2020 17:36:56

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:14:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:19
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
User closed query 'Per DM CLR: Con Med stop date is after the stop date of the AE. It is not expected that this treatment would continue past the AE. Please review and reconcile Con Med and AE stop dates as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Jan 2021 09:21:32
Query 'Per DM CLR: Con Med stop date is after the stop date of the AE. It is not expected that this treatment would continue past the AE. Please review and reconcile Con Med and AE stop dates as appropriate. ' answered with 'data correct as is' (Site from DM).	Peter Jacob (b) (4) (b) (4)	19 Jan 2021 20:42:35
DataPoint Un-verified.	Peter Jacob (b) (4) (b) (4)	19 Jan 2021 20:42:16
User entered '05 Sep 2020' reason for change: Data Entry Error	Peter Jacob (b) (4) (b) (4)	19 Jan 2021 20:42:16
User opened query 'Per DM CLR: Con Med stop date is after the stop date of the AE. It is not expected that this treatment would continue past the AE. Please review and reconcile Con Med and AE stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 09:09:54
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:23:37
User entered '5 Sep 2020'	Mary Sergalis (b) (4)	18 Nov 2020 17:36:56

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:14:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:19
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:23:38
User entered 'No (N)'	Mary Sergalis (b) (4)	18 Nov 2020 17:36:56

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:14:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:19
User entered empty.	System	18 Nov 2020 17:36:56

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:19
User entered empty.	System	18 Nov 2020 17:36:56

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:19
User entered empty.	System	18 Nov 2020 17:36:56

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:14:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:15
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:44:15
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN W/OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 03:46:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 03:46:52
Data point term sent to Coder	System	18 Nov 2020 17:38:38
User entered 'Oxycodone/Acetaminophen 5/325'	Mary Sergalis (b) (4)	18 Nov 2020 17:38:02

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:14:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:15
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:24:36
User entered 'No (N)'	Mary Sergalis (b) (4)	18 Nov 2020 17:38:02

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:14:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:15
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:24:39
User entered 'Right Lower Abdominal Pain'	Mary Sergalis (b) (4)	18 Nov 2020 17:38:02

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:14:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:15
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:24:40
User entered 'l'	Mary Sergalis (b) (4)	18 Nov 2020 17:38:02

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:14:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:15
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:24:43
User entered 'tablet (TABLET)'	Mary Sergalis (b) (4)	18 Nov 2020 17:38:02

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:14:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:15
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:24:44
User entered empty.	Mary Sergalis (b) (4)	18 Nov 2020 17:38:02

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:14:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:15
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:24:45
User entered 'as needed (PRN)'	Mary Sergalis (b) (4)	18 Nov 2020 17:38:02

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:14:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:15
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:24:47
User entered empty.	Mary Sergalis (b) (4)	18 Nov 2020 17:38:02

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:14:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:15
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:24:48
User entered 'Oral (ORAL)'	Mary Sergalis (b) (4)	18 Nov 2020 17:38:02

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:14:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:15
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:25:00
User entered empty.	Mary Sergalis (b) (4)	18 Nov 2020 17:38:02

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:14:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:15
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4)	
	Peter Jacob (b) (4)	19 Jan 2021 20:43:43
	(b) (4)	
User entered '02 Sep 2020' reason for change: Data Entry Error	Peter Jacob (b) (4)	19 Jan 2021 20:43:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 15:25:01
User entered '2 Sep 2020'	Mary Sergalis (b) (4)	18 Nov 2020 17:38:02

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:14:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:15
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:25:03
User entered '0'	Mary Sergalis (b) (4)	18 Nov 2020 17:38:02

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:14:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:15
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:25:04
User entered 'No (N)'	Mary Sergalis (b) (4)	18 Nov 2020 17:38:02

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:14:43

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:15
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
User closed query 'Per DM CLR: Con Med stop date is after the stop date of the AE. It is not expected that this treatment would continue past the AE. Please review and reconcile Con Med and AE stop dates as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Jan 2021 09:21:39
Query 'Per DM CLR: Con Med stop date is after the stop date of the AE. It is not expected that this treatment would continue past the AE. Please review and reconcile Con Med and AE stop dates as appropriate. ' answered with 'data correct as is' (Site from DM).	Peter Jacob (b) (4) (b) (4)	19 Jan 2021 20:43:53
DataPoint Un-verified.	Peter Jacob (b) (4) (b) (4)	19 Jan 2021 20:43:43
User entered '05 Sep 2020' reason for change: Data Entry Error	Peter Jacob (b) (4) (b) (4)	19 Jan 2021 20:43:43
User opened query 'Per DM CLR: Con Med stop date is after the stop date of the AE. It is not expected that this treatment would continue past the AE. Please review and reconcile Con Med and AE stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 09:10:27
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:25:06
User entered '5 Sep 2020'	Mary Sergalis (b) (4)	18 Nov 2020 17:38:02

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:14:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:15
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:25:07
User entered 'No (N)'	Mary Sergalis (b) (4)	18 Nov 2020 17:38:02

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:14:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:15
User entered empty.	System	18 Nov 2020 17:38:02

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:15
User entered empty.	System	18 Nov 2020 17:38:02

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:15
User entered empty.	System	18 Nov 2020 17:38:02

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:14:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:11
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:44:23
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 04:00:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 04:00:52
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 03:45:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 03:45:55
Data point term sent to Coder	System	18 Nov 2020 17:39:39
User entered 'Pantoprazole'	Mary Sergalis (b) (4) (b) (4) (b) (4)	18 Nov 2020 17:39:16

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:14:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:11
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:25:30
User entered 'No (N)'	Mary Sergalis (b) (4)	18 Nov 2020 17:39:16

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:14:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:11
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:25:32
User entered 'Gastroesophageal Reflux disease'	Mary Sergalis (b) (4)	18 Nov 2020 17:39:16

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:14:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:11
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:25:49
User entered '40'	Mary Sergalis (b) (4)	18 Nov 2020 17:39:16

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:14:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:11
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:25:48
User entered 'mg (mg)'	Mary Sergalis (b) (4)	18 Nov 2020 17:39:16

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:14:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:11
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:25:51
User entered empty.	Mary Sergalis (b) (4)	18 Nov 2020 17:39:16

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:14:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:11
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:25:52
User entered 'once daily (QD)'	Mary Sergalis (b) (4)	18 Nov 2020 17:39:16

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:14:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:11
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:25:58
User entered empty.	Mary Sergalis (b) (4)	18 Nov 2020 17:39:16

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:14:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:11
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:25:59
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	Mary Sergalis (b) (4)	18 Nov 2020 17:39:16

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:14:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:11
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:26:02
User entered empty.	Mary Sergalis (b) (4)	18 Nov 2020 17:39:16

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:14:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:11
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
User closed query 'Per DM CLR: Con Med PANTOPRAZOLE was added/changed on 2 SEP 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen.' (Site from DM). Query 'Per DM CLR: Con Med PANTOPRAZOLE was added/changed on 2 SEP 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen.' answered with 'data correct as is' (Site from DM). DataPoint Un-verified.	(b) (4) (b) (4), (b) (6) Peter Jacob (b) (4) (b) (4)	20 Jan 2021 09:21:46 19 Jan 2021 20:45:21
User entered '02 Sep 2020' reason for change: Data Entry Error	Peter Jacob (b) (4) (b) (4)	19 Jan 2021 20:44:11 19 Jan 2021 20:44:11
User opened query 'Per DM CLR: Con Med PANTOPRAZOLE was added/changed on 2 SEP 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 09:10:54 23 Nov 2020 15:26:03
User entered '2 Sep 2020'	Mary Sergalis (b) (4)	18 Nov 2020 17:39:16

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:14:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:11
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:26:08
User entered '0'	Mary Sergalis (b) (4)	18 Nov 2020 17:39:16

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:14:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:11
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:26:09
User entered 'No (N)'	Mary Sergalis (b) (4)	18 Nov 2020 17:39:16

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:14:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:11
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4)	
	Peter Jacob (b) (4)	19 Jan 2021 20:44:11
	(b) (4)	
User entered '05 Sep 2020' reason for change: Data Entry Error	Peter Jacob (b) (4)	19 Jan 2021 20:44:11
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 15:26:11
User entered '5 Sep 2020'	Mary Sergalis (b) (4)	18 Nov 2020 17:39:16

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:14:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:11
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:26:12
User entered 'No (N)'	Mary Sergalis (b) (4)	18 Nov 2020 17:39:16

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:14:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:11
User entered '1'	System	18 Nov 2020 17:39:16

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:11
User entered '1'	System	18 Nov 2020 17:39:16

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:11
User entered '804 (804)'	System	18 Nov 2020 17:39:16

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:14:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:07
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:44:30
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 03:35:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 03:35:03
Data point term sent to Coder	System	18 Nov 2020 17:41:41
User entered 'Zofran'	Mary Sergalis (b) (4) (b) (4) (b) (4)	18 Nov 2020 17:40:50

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:14:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:07
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:27:05
User entered 'No (N)'	Mary Sergalis (b) (4)	18 Nov 2020 17:40:50

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:14:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:07
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 13:44:29
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' answered with 'Data updated.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:32:48
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 09:13:07
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:27:07
User entered 'Nausea'	Mary Sergalis (b) (4)	18 Nov 2020 17:40:50

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:14:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:07
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:27:08
User entered '4'	Mary Sergalis (b) (4)	18 Nov 2020 17:40:50

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:14:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:07
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:27:10
User entered 'mg (mg)'	Mary Sergalis (b) (4)	18 Nov 2020 17:40:50

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:14:43

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:07
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:27:11
User entered empty.	Mary Sergalis (b) (4)	18 Nov 2020 17:40:50

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:14:43

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:07
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:27:12
User entered 'as needed (PRN)'	Mary Sergalis (b) (4)	18 Nov 2020 17:40:50

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:14:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:07
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:27:15
User entered empty.	Mary Sergalis (b) (4)	18 Nov 2020 17:40:50

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:14:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:07
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:27:16
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	Mary Sergalis (b) (4)	18 Nov 2020 17:40:50

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:14:43

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:07
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:27:18
User entered empty.	Mary Sergalis (b) (4)	18 Nov 2020 17:40:50

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:14:43

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:07
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4)	
	Peter Jacob (b) (4)	19 Jan 2021 20:47:09
	(b) (4)	
User entered '02 Sep 2020' reason for change: Data Entry Error	Peter Jacob (b) (4)	19 Jan 2021 20:47:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 15:27:20
User entered '2 Sep 2020'	Mary Sergalis (b) (4)	18 Nov 2020 17:40:50

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:14:43

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:07
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:27:21
User entered '0'	Mary Sergalis (b) (4)	18 Nov 2020 17:40:50

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:14:43

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:07
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:27:23
User entered 'No (N)'	Mary Sergalis (b) (4)	18 Nov 2020 17:40:50

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:14:43

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:07
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Un-verified.	(b) (4)	
	Peter Jacob (b) (4)	19 Jan 2021 20:47:09
	(b) (4)	
User entered '05 Sep 2020' reason for change: Data Entry Error	Peter Jacob (b) (4)	19 Jan 2021 20:47:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 15:27:24
User entered '5 Sep 2020'	Mary Sergalis (b) (4)	18 Nov 2020 17:40:50

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:14:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:07
User signature succeeded.	Mira Baron (b) (4)	05 Apr 2021 18:40:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:27:26
User entered 'No (N)'	Mary Sergalis (b) (4)	18 Nov 2020 17:40:50

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:14:43

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:07
User entered empty.	System	18 Nov 2020 17:40:50

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:07
User entered empty.	System	18 Nov 2020 17:40:50

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:14:43

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:07
User entered empty.	System	18 Nov 2020 17:40:50

US3372184

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:14:43

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:06:13
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:08:43
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Mary Sergalis (b) (4)	19 Oct 2020 18:51:11
User entered 'No (N)'	(b) (4) Peter Jacob (b) (4)	14 Oct 2020 18:53:38

US3372184

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:14:43

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:08:43
	(b) (4)	
User entered '2 Sep 2020'	Mary Sergalis (b) (4)	19 Oct 2020 18:51:39

US3372184

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:14:43

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:08:43
	(b) (4)	
User entered 'Appendectomy'	Mary Sergalis (b) (4)	19 Oct 2020 18:51:39

US3372184

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:14:43

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:08:43
	(b) (4)	
User entered 'Adverse Event (AE)'	Mary Sergalis (b) (4)	19 Oct 2020 18:51:39

US3372184

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:14:43

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	16 Feb 2021 18:08:43
	(b) (4)	
User entered empty.	Mary Sergalis (b) (4)	19 Oct 2020 18:51:39

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'USA-US056-2020-MRNA-1273-P301000002'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'Yes (Y)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'No (N)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'No (N)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'Yes (Y)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'No (N)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'No (N)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'No (N)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:17:39
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:14
Amendment Manager: User entered 'Mira'	System	14 Sep 2020 22:03:33

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:17:39
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:14
Amendment Manager: User entered 'Baron'	System	14 Sep 2020 22:03:33

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:17:39
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:14
Amendment Manager: User entered '2277 Palm beach Lakes Blvd'	System	14 Sep 2020 22:03:33

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:17:39
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:14
Amendment Manager: User entered 'West Palm Beach'	System	14 Sep 2020 22:03:33

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:17:39
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:14
Amendment Manager: User entered '33409'	System	14 Sep 2020 22:03:33

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:17:39
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:35:04
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:14
User entered 'US' (non-conformant).	System	07 Sep 2020 16:56:00

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	08 Mar 2021 17:12:27
Signature has been broken.	System	26 Feb 2021 03:07:26
User entered '6'	System	26 Feb 2021 03:07:26
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
	(b) (4)	
User entered '5'	System	11 Nov 2020 14:08:22
User entered '4'	System	03 Nov 2020 18:09:37
User entered '3'	System	27 Oct 2020 12:46:32
User entered '2'	System	20 Oct 2020 15:17:45
User entered '1'	System	07 Sep 2020 16:56:00

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'USA-US056-2020-MRNA-1273-P301000002'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'Yes (Y)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'No (N)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'No (N)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'Yes (Y)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'No (N)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'No (N)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'No (N)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:17:39
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:14
Amendment Manager: User entered 'Mira'	System	14 Sep 2020 22:03:33

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:17:39
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:14
Amendment Manager: User entered 'Baron'	System	14 Sep 2020 22:03:33

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:17:39
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:14
Amendment Manager: User entered '2277 Palm beach Lakes Blvd'	System	14 Sep 2020 22:03:33

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:17:39
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:14
Amendment Manager: User entered 'West Palm Beach'	System	14 Sep 2020 22:03:33

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:17:39
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:14
Amendment Manager: User entered '33409'	System	14 Sep 2020 22:03:33

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:17:39
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:35:04
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:14
User entered 'US' (non-conformant).	System	07 Sep 2020 16:56:00

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	08 Mar 2021 17:12:27
Signature has been broken.	System	26 Feb 2021 03:07:26
User entered '6'	System	26 Feb 2021 03:07:26
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
	(b) (4)	
User entered '5'	System	11 Nov 2020 14:08:22
User entered '4'	System	03 Nov 2020 18:09:37
User entered '3'	System	27 Oct 2020 12:46:32
User entered '2'	System	20 Oct 2020 15:17:45
User entered '1'	System	07 Sep 2020 16:56:00

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:14:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
User entered '07/Sep/2020 12:55'	System	07 Sep 2020 16:56:00

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:14:43

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.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 15:17:39
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:14
User entered 'I'	(b) (4), (b) (6)	07 Sep 2020 16:56:00

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'USA-US056-2020-MRNA-1273-P301000002'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'Yes (Y)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'No (N)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'No (N)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'Yes (Y)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'No (N)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'No (N)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'No (N)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:17:39
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:14
Amendment Manager: User entered 'Mira'	System	14 Sep 2020 22:03:33

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:17:39
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:14
Amendment Manager: User entered 'Baron'	System	14 Sep 2020 22:03:33

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:17:39
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:14
Amendment Manager: User entered '2277 Palm beach Lakes Blvd'	System	14 Sep 2020 22:03:33

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:17:39
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:14
Amendment Manager: User entered 'West Palm Beach'	System	14 Sep 2020 22:03:33

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:17:39
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:14
Amendment Manager: User entered '33409'	System	14 Sep 2020 22:03:33

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:17:39
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:35:04
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:14
User entered 'US' (non-conformant).	System	07 Sep 2020 16:56:00

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	08 Mar 2021 17:12:27
Signature has been broken.	System	26 Feb 2021 03:07:26
User entered '6'	System	26 Feb 2021 03:07:26
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
	(b) (4)	
User entered '5'	System	11 Nov 2020 14:08:22
User entered '4'	System	03 Nov 2020 18:09:37
User entered '3'	System	27 Oct 2020 12:46:32
User entered '2'	System	20 Oct 2020 15:17:45
User entered '1'	System	07 Sep 2020 16:56:00

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:14:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:23:16
User entered '20/Oct/2020 15:17'	System	20 Oct 2020 15:17:45

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:14:43

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.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:23:17
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 15:17:48
User entered 'I'	(b) (4), (b) (6)	20 Oct 2020 15:17:45

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'USA-US056-2020-MRNA-1273-P301000002'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'Yes (Y)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'No (N)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'No (N)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'Yes (Y)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'No (N)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'No (N)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'No (N)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:17:39
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:14
Amendment Manager: User entered 'Mira'	System	14 Sep 2020 22:03:33

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:17:39
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:14
Amendment Manager: User entered 'Baron'	System	14 Sep 2020 22:03:33

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:17:39
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:14
Amendment Manager: User entered '2277 Palm beach Lakes Blvd'	System	14 Sep 2020 22:03:33

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:17:39
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:14
Amendment Manager: User entered 'West Palm Beach'	System	14 Sep 2020 22:03:33

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:17:39
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:14
Amendment Manager: User entered '33409'	System	14 Sep 2020 22:03:33

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:17:39
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:35:04
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:14
User entered 'US' (non-conformant).	System	07 Sep 2020 16:56:00

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	08 Mar 2021 17:12:27
Signature has been broken.	System	26 Feb 2021 03:07:26
User entered '6'	System	26 Feb 2021 03:07:26
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
	(b) (4)	
User entered '5'	System	11 Nov 2020 14:08:22
User entered '4'	System	03 Nov 2020 18:09:37
User entered '3'	System	27 Oct 2020 12:46:32
User entered '2'	System	20 Oct 2020 15:17:45
User entered '1'	System	07 Sep 2020 16:56:00

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:14:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:23:28
User entered '27/Oct/2020 08:46'	System	27 Oct 2020 12:46:32

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:14:43

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.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:23:30
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 18:09:08
User entered 'I'	(b) (4), (b) (6)	27 Oct 2020 12:46:32

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'USA-US056-2020-MRNA-1273-P301000002'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'Yes (Y)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'No (N)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'No (N)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'Yes (Y)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'No (N)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'No (N)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'No (N)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:17:39
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:14
Amendment Manager: User entered 'Mira'	System	14 Sep 2020 22:03:33

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:17:39
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:14
Amendment Manager: User entered 'Baron'	System	14 Sep 2020 22:03:33

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:17:39
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:14
Amendment Manager: User entered '2277 Palm beach Lakes Blvd'	System	14 Sep 2020 22:03:33

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:17:39
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:14
Amendment Manager: User entered 'West Palm Beach'	System	14 Sep 2020 22:03:33

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:17:39
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:14
Amendment Manager: User entered '33409'	System	14 Sep 2020 22:03:33

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:17:39
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:35:04
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:14
User entered 'US' (non-conformant).	System	07 Sep 2020 16:56:00

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	08 Mar 2021 17:12:27
Signature has been broken.	System	26 Feb 2021 03:07:26
User entered '6'	System	26 Feb 2021 03:07:26
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
	(b) (4)	
User entered '5'	System	11 Nov 2020 14:08:22
User entered '4'	System	03 Nov 2020 18:09:37
User entered '3'	System	27 Oct 2020 12:46:32
User entered '2'	System	20 Oct 2020 15:17:45
User entered '1'	System	07 Sep 2020 16:56:00

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:14:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 19:23:46
User entered '03/Nov/2020 18:09'	System	03 Nov 2020 18:09:37

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:14:43

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.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 14:08:10
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:23:47
User entered 'I'	(b) (4), (b) (6)	03 Nov 2020 18:09:37

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'USA-US056-2020-MRNA-1273-P301000002'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'Yes (Y)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'No (N)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'No (N)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'Yes (Y)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'No (N)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'No (N)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'No (N)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:17:39
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:14
Amendment Manager: User entered 'Mira'	System	14 Sep 2020 22:03:33

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:17:39
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:14
Amendment Manager: User entered 'Baron'	System	14 Sep 2020 22:03:33

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:17:39
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:14
Amendment Manager: User entered '2277 Palm beach Lakes Blvd'	System	14 Sep 2020 22:03:33

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:17:39
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:14
Amendment Manager: User entered 'West Palm Beach'	System	14 Sep 2020 22:03:33

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:17:39
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:14
Amendment Manager: User entered '33409'	System	14 Sep 2020 22:03:33

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:17:39
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:35:04
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:14
User entered 'US' (non-conformant).	System	07 Sep 2020 16:56:00

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	08 Mar 2021 17:12:27
Signature has been broken.	System	26 Feb 2021 03:07:26
User entered '6'	System	26 Feb 2021 03:07:26
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
	(b) (4)	
User entered '5'	System	11 Nov 2020 14:08:22
User entered '4'	System	03 Nov 2020 18:09:37
User entered '3'	System	27 Oct 2020 12:46:32
User entered '2'	System	20 Oct 2020 15:17:45
User entered '1'	System	07 Sep 2020 16:56:00

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:14:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:07:36
User entered '11/Nov/2020 14:08'	System	11 Nov 2020 14:08:22

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:14:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:45:56
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 03:07:17
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
User entered 'I'	(b) (4), (b) (6)	11 Nov 2020 14:08:22

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'USA-US056-2020-MRNA-1273-P301000002'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'Yes (Y)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'No (N)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'No (N)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'Yes (Y)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'No (N)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'No (N)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'No (N)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:17:39
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:14
Amendment Manager: User entered 'Mira'	System	14 Sep 2020 22:03:33

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:17:39
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:14
Amendment Manager: User entered 'Baron'	System	14 Sep 2020 22:03:33

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:17:39
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:14
Amendment Manager: User entered '2277 Palm beach Lakes Blvd'	System	14 Sep 2020 22:03:33

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:17:39
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:14
Amendment Manager: User entered 'West Palm Beach'	System	14 Sep 2020 22:03:33

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:17:39
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:14
Amendment Manager: User entered '33409'	System	14 Sep 2020 22:03:33

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:17:39
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:35:04
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:14
User entered 'US' (non-conformant).	System	07 Sep 2020 16:56:00

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	08 Mar 2021 17:12:27
Signature has been broken.	System	26 Feb 2021 03:07:26
User entered '6'	System	26 Feb 2021 03:07:26
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
	(b) (4)	
User entered '5'	System	11 Nov 2020 14:08:22
User entered '4'	System	03 Nov 2020 18:09:37
User entered '3'	System	27 Oct 2020 12:46:32
User entered '2'	System	20 Oct 2020 15:17:45
User entered '1'	System	07 Sep 2020 16:56:00

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:14:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:45:56
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:21:44
User entered '26/Feb/2021 03:07'	(b) (4) System	26 Feb 2021 03:07:26

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:14:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:45:56
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:21:44
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:12:17
User entered 'I'	(b) (4), (b) (6)	26 Feb 2021 03:07:26

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'USA-US056-2020-MRNA-1273-P301000002'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'Yes (Y)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'No (N)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'No (N)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'Yes (Y)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'No (N)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'No (N)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Sep 2020 14:34:14
Reviewed for Safety.	(b) (4), (b) (6)	07 Sep 2020 16:55:54
User entered 'No (N)'	System	07 Sep 2020 16:55:11

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:17:39
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:14
Amendment Manager: User entered 'Mira'	System	14 Sep 2020 22:03:33

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:17:39
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:14
Amendment Manager: User entered 'Baron'	System	14 Sep 2020 22:03:33

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:17:39
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:14
Amendment Manager: User entered '2277 Palm beach Lakes Blvd'	System	14 Sep 2020 22:03:33

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:17:39
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:14
Amendment Manager: User entered 'West Palm Beach'	System	14 Sep 2020 22:03:33

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:17:39
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:14
Amendment Manager: User entered '33409'	System	14 Sep 2020 22:03:33

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 15:17:39
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:35:04
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:14
User entered 'US' (non-conformant).	System	07 Sep 2020 16:56:00

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 17:14:43

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	08 Mar 2021 17:12:27
Signature has been broken.	System	26 Feb 2021 03:07:26
User entered '6'	System	26 Feb 2021 03:07:26
User signature succeeded.	Mira Baron (b) (4)	17 Feb 2021 02:51:10
	(b) (4)	
User entered '5'	System	11 Nov 2020 14:08:22
User entered '4'	System	03 Nov 2020 18:09:37
User entered '3'	System	27 Oct 2020 12:46:32
User entered '2'	System	20 Oct 2020 15:17:45
User entered '1'	System	07 Sep 2020 16:56:00

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 17:14:43

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:45:56
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:21:44
User entered '08/Mar/2021 11:12'	(b) (4) System	08 Mar 2021 17:12:27

US3372184

Folder: SAE USA-US056-2020-MRNA-1273-P301000002

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 17:14:43

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:45:56
User signature succeeded.	Mira Baron (b) (4)	16 Mar 2021 19:21:44
User entered 'I'	(b) (4) (b) (4), (b) (6)	08 Mar 2021 17:12:27