

US3372184 (Prod: Palm Beach Research Center)

Generated By: (b) (6)

Generated On: 26 Nov 2020 11:01:38

All time stamps listed in this document are displayed in GMT

US3372184

Form: Participant Creation

Generated On: 26 Nov 2020 11:01:38

[Participant ID](#)

US3372184

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

US3372184

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:01:38

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	19 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

US3372184

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:38

Date of Birth (MMM yyyy)	(b) (6) 1947
Age	72
Age Units	YEARS
Age (Derived)	72
Sex	Female ☐ Male ☒
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
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

Generated On: 26 Nov 2020 11:01:38

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 ☐
	Amendment 2 ☒
	Amendment 3 ☐
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:01:38

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:01:38

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:38

Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN UNK 2009
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)

Generated On: 26 Nov 2020 11:01:38

Condition	ESSENTIAL TREMORS
Start date (dd MMM yyyy)	UN UNK 1997
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)

Generated On: 26 Nov 2020 11:01:38

Condition	BENIGN PROSTATIC HYPERPLASIA (BPH)
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)

Generated On: 26 Nov 2020 11:01:38

Condition	URINARY RETENTION
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)

Generated On: 26 Nov 2020 11:01:38

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 1970
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)

Generated On: 26 Nov 2020 11:01:38

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)

Generated On: 26 Nov 2020 11:01:38

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 1974
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)

Generated On: 26 Nov 2020 11:01:38

Condition	SINUSITIS
Start date (dd MMM yyyy)	UN UNK 1994
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)

Generated On: 26 Nov 2020 11:01:38

Condition	ALLERGY - ENVIRONMENTAL
Start date (dd MMM yyyy)	UN UNK 1994
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)

Generated On: 26 Nov 2020 11:01:38

Condition	GENITAL HERPES
Start date (dd MMM yyyy)	UN UNK 1958
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)

Generated On: 26 Nov 2020 11:01:38

Condition	ERECTILE DYSFUNCTION
Start date (dd MMM yyyy)	UN UNK 1999
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)

Generated On: 26 Nov 2020 11:01:38

Condition	GENERALIZED OSTEOARTHRITIS
Start date (dd MMM yyyy)	UN UNK 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)

Generated On: 26 Nov 2020 11:01:38

Condition	INTERNAL HEMORRHOIDS
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)

Generated On: 26 Nov 2020 11:01:38

Condition	OSTEOPENIA
Start date (dd MMM yyyy)	UN UNK 1999
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)

Generated On: 26 Nov 2020 11:01:38

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 ☒ No ☐
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)

Generated On: 26 Nov 2020 11:01:38

Condition	CATARACTS BILATERAL
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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)

Generated On: 26 Nov 2020 11:01:38

Condition	CATARACTS SURGERY BILATERAL
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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)

Generated On: 26 Nov 2020 11:01:38

Condition	SUBDURAL HEMATOMA
Start date (dd MMM yyyy)	UN UNK 2007
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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)

Generated On: 26 Nov 2020 11:01:38

Condition	BURR HOLE
Start date (dd MMM yyyy)	UN UNK 2007
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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)

Generated On: 26 Nov 2020 11:01:38

Condition	VOCAL CORD POLYPS
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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: Medical History (21)

Generated On: 26 Nov 2020 11:01:38

Condition	VOCAL CORD POLYPECTOMY
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
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

Generated On: 26 Nov 2020 11:01:38

Were vital signs assessed?	Yes ☒
	No ☐
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 ☐
	Axillary ☐
	Other ☐
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

Generated On: 26 Nov 2020 11:01:38

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

Generated On: 26 Nov 2020 11:01:38

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

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs) False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:38

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

Generated On: 26 Nov 2020 11:01:38

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	19 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:38

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

Generated On: 26 Nov 2020 11:01:38

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:38

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
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 ☒ Axillary ☐ Other ☐
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)

Generated On: 26 Nov 2020 11:01:38

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
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 ☒ Axillary ☐ Other ☐
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

Generated On: 26 Nov 2020 11:01:38

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

Generated On: 26 Nov 2020 11:01:38

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

Generated On: 26 Nov 2020 11:01:38

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	19 AUG 2020
Collection time (<i>00:00-23:59</i>)	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

Generated On: 26 Nov 2020 11:01:38

Collection date (<i>dd MMM yyyy</i>)			19 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	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

Generated On: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:38

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:38

Yes ☐	
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: 26 Nov 2020 11:01:38

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 ☒

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:38

Yes ☐	
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: 26 Nov 2020 11:01:38

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 ☒

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:38

Yes ☐	
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: 26 Nov 2020 11:01:38

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 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:38

Yes ☐	
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: 26 Nov 2020 11:01:38

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 ☒

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:38

Yes ☐	
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: 26 Nov 2020 11:01:38

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 ☒

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:38

Yes ☐	
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

Generated On: 26 Nov 2020 11:01:38

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

Generated On: 26 Nov 2020 11:01:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372184

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:38

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

Generated On: 26 Nov 2020 11:01:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372184

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:38

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

Generated On: 26 Nov 2020 11:01:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372184

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:01:38

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	22 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3372184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:38

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
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 ☒
	Axillary ☐
	Other ☐
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)

Generated On: 26 Nov 2020 11:01:38

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
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 ☒
	Axillary ☐
	Other ☐
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

Generated On: 26 Nov 2020 11:01:38

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

Generated On: 26 Nov 2020 11:01:38

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

Generated On: 26 Nov 2020 11:01:38

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	22 SEP 2020
Collection time (<i>00:00-23:59</i>)	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

Generated On: 26 Nov 2020 11:01:38

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

Generated On: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

Yes ☐	
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: 26 Nov 2020 11:01:38

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 ☒

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:38

Yes ☐	
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: 26 Nov 2020 11:01:38

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 ☐

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:38

		Yes ☐
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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

Yes ☐	
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: 26 Nov 2020 11:01:38

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 ☒

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:38

Yes ☐	
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: 26 Nov 2020 11:01:38

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 ☒

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:38

Yes ☐	
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

Generated On: 26 Nov 2020 11:01:38

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

Generated On: 26 Nov 2020 11:01:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372184

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:38

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

Generated On: 26 Nov 2020 11:01:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372184

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:38

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

Generated On: 26 Nov 2020 11:01:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372184

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:01:38

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	14 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3372184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:38

Were vital signs assessed?	Yes ☐
	No ☒
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3372184

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:38

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

Generated On: 26 Nov 2020 11:01:38

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	14 OCT 2020
Collection time (<i>00:00-23:59</i>)	14:14 (24 HR)
Collection date and time (derived)	14 OCT 2020 14:14

US3372184

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2020 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2020 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2020 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2020 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 11:01:38

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

13 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2020 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 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: 26 Nov 2020 11:01:38

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 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: 26 Nov 2020 11:01:38

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 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: 26 Nov 2020 11:01:38

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:01:38

Please contact your study clinic immediately. Click below to confirm that you have read this 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	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: 26 Nov 2020 11:01:38

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 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: 26 Nov 2020 11:01:38

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 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: 26 Nov 2020 11:01:38

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 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: 26 Nov 2020 11:01:38

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:01:38

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

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: 26 Nov 2020 11:01:38

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 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: 26 Nov 2020 11:01:38

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2021 00:01

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26 JAN 2021 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 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: 26 Nov 2020 11:01:38

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 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: 26 Nov 2020 11:01:38

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:01:38

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

12 FEB 2021 00:01

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16 FEB 2021 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 FEB 2021 00:01

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23 FEB 2021 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:01:38

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:01:38

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 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: 26 Nov 2020 11:01:38

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:01:38

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

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: 26 Nov 2020 11:01:38

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 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: 26 Nov 2020 11:01:38

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:01:38

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:01:38

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 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: 26 Nov 2020 11:01:38

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2021 00:01

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13 APR 2021 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 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: 26 Nov 2020 11:01:38

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 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: 26 Nov 2020 11:01:38

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 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: 26 Nov 2020 11:01:38

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 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: 26 Nov 2020 11:01:38

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

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

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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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

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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 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: 26 Nov 2020 11:01:38

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 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: 26 Nov 2020 11:01:38

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 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: 26 Nov 2020 11:01:38

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 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: 26 Nov 2020 11:01:38

TIMEPOINT

DAY 348

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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

13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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

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: 26 Nov 2020 11:01:38

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 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: 26 Nov 2020 11:01:38

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

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

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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 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: 26 Nov 2020 11:01:38

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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

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: 26 Nov 2020 11:01:38

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 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: 26 Nov 2020 11:01:38

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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

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: 26 Nov 2020 11:01:38

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 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: 26 Nov 2020 11:01:38

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 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: 26 Nov 2020 11:01:38

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

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

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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 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: 26 Nov 2020 11:01:38

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

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01 FEB 2022 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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

Date and time of submission

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04 FEB 2022 00:01

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08 FEB 2022 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

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)

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11 FEB 2022 00:01

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15 FEB 2022 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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

Date and time of submission

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18 FEB 2022 00:01

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22 FEB 2022 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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

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01 MAR 2022 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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Date and time of submission

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08 MAR 2022 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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

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15 MAR 2022 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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

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18 MAR 2022 00:01

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22 MAR 2022 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

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29 MAR 2022 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

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05 APR 2022 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

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

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

08 APR 2022 00:01

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12 APR 2022 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

TIMEPOINT

DAY 607

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Date and time of submission

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19 APR 2022 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

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 ☐ Yes ☐

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

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

Date and time of submission

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26 APR 2022 23:59

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

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 ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 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: 26 Nov 2020 11:01:38

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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

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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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

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: 26 Nov 2020 11:01:38

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 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: 26 Nov 2020 11:01:38

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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

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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 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: 26 Nov 2020 11:01:38

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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

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: 26 Nov 2020 11:01:38

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 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: 26 Nov 2020 11:01:38

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 11:01:38

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 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: 26 Nov 2020 11:01:38

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

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 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: 26 Nov 2020 11:01:38

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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

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: 26 Nov 2020 11:01:38

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 ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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: 26 Nov 2020 11:01:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2022 23:59

US3372184

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:38

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

Generated On: 26 Nov 2020 11:01:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3372184

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:38

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 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:38

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3372184

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:01:38

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled ☐
	Clinical Visit - Unscheduled ☐
	Safety Call ☐
	Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☐
	No ☐

US3372184

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:01:38

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3372184

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:01:38

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:38

AEID	USA-US056-2020-MRNA-1273-P30 1000002
Adverse event	APPENDICITIS
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)	02 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	02 SEP 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	True
Hospital Admission Date (dd MMM yyyy)	02 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	06 SEP 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	
v6.020 DTW (1102)	353 of 2467

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:38

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☐ Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
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
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	0

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:38

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 ☐
Number of Days in ICU	
v6.020 DTW (1102)	
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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:38

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☐ Related ☐ Not Applicable ☒
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☐ Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
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)	_____

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:01:38

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

Yes ☒

No ☐

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

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:38

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 ☐ Intraocular ☐

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:01:38

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2012	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:38

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 ☐ Intramuscular ☐

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:01:38

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 1999
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:38

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 ☐ Intraocular ☐

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:01:38

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

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:38

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 ☐ Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:01:38

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2019
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:01:38

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 ☐ Intramuscular ☐

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:01:38

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2017
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:01:38

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 ☐ Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:01:38

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2005
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	2	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:01:38

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 ☐ Intramuscular ☐

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:01:38

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK	1995
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:01:38

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 ☐ Intramuscular ☐

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:01:38

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2010
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:01:38

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 ☐ Intramuscular ☐

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:01:38

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

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:01:38

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 ☐ Intramuscular ☐

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:01:38

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2009
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:01:38

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 ☐ Intramuscular ☐

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:01:38

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 1999
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:01:38

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 ☐ Intraocular ☐

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:01:38

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2002
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:01:38

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 ☐ Intraocular ☐

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:01:38

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 1995
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:01:38

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 ☐ Intraocular ☐

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 11:01:38

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

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:01:38

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 ☐ Intraocular ☐

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 11:01:38

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

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:01:38

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 ☐ Intramuscular ☐

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:01:38

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK	1975
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:01:38

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 ☐ Intramuscular ☐

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 11:01:38

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2009
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:01:38

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 ☐ Intramuscular ☐

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:01:38

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2009
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:01:38

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 ☐ Subcutaneous ☐

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 11:01:38

	Transdermal	☐
	Intraocular	☐
	Intramuscular	☒
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2011
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	UN	UNK 2011
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:01:38

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 ☐ Intraocular ☐

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 11:01:38

	Intramuscular	☒
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	UN UNK 2015	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:01:38

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 ☐ Intraocular ☐

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 11:01:38

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

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:01:38

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 ☐ Intraocular ☐

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 11:01:38

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

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 11:01:38

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 ☐ Intraocular ☐

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 11:01:38

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

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 11:01:38

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 ☐ Intraocular ☐

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 11:01:38

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	28 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)		28 AUG 2020
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 11:01:38

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 ☐

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 11:01:38

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	07 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	10 SEP 2020	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☒	

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 11:01:38

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 ☐ Intramuscular ☐

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 11:01:38

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☐
Vaginal	☐
Rectal	☐
Intravenous	☒
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☐
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	02 SEP 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ☒
If not Ongoing, End date (dd MMM yyyy)	03 SEP 2020
Was this medication taken for solicited event?	Yes ☐ No ☒
Separate Dosage Number (derived)	3
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ☒

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 11:01:38

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 ☐
	Intramuscular ☒

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 11:01:38

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

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 11:01:38

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 ☐ Intramuscular ☐

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 11:01:38

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☒
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		02 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		05 SEP 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 11:01:38

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 ☐ Intraocular ☐

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 11:01:38

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☒
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	2 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)		5 SEP 2020
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☒	

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 11:01:38

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 ☐ Intraocular ☐

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 11:01:38

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☒
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	2 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)		5 SEP 2020
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☐	

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 26 Nov 2020 11:01:38

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 ☐

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 26 Nov 2020 11:01:38

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	2 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 5 SEP 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 26 Nov 2020 11:01:38

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 ☐ Intraocular ☐

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 26 Nov 2020 11:01:38

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☒
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	2 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	5 SEP 2020	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☒	

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 26 Nov 2020 11:01:38

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 ☐ Intramuscular ☐

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 26 Nov 2020 11:01:38

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☒
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		2 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		5 SEP 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3372184

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:01:38

[Were any concomitant procedures performed?](#)

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3372184

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 11:01:38

Procedure/Surgery date (<i>dd MMM yyyy</i>)	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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

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

Generated On: 26 Nov 2020 11:01:38

SAEID	USA-US056-2020-MRNA-1273-P301000002
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
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)	5

US3372184

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

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:01:38

SAEID	USA-US056-2020-MRNA-1273-P301000002
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
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)	5
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)

Generated On: 26 Nov 2020 11:01:38

SAEID	USA-US056-2020-MRNA-1273-P301000002
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
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)	5
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)

Generated On: 26 Nov 2020 11:01:38

SAEID	USA-US056-2020-MRNA-1273-P301000002
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
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)	5
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)

Generated On: 26 Nov 2020 11:01:38

SAEID	USA-US056-2020-MRNA-1273-P301000002
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
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)	5
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)

Generated On: 26 Nov 2020 11:01:38

SAEID	USA-US056-2020-MRNA-1273-P301000002
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
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)	5
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

Audit

US3372184 (Prod: Palm Beach Research Center)

US3372184

Form: Participant Creation

Generated On: 26 Nov 2020 11:01:38

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3372184'	RWS_ENDPOINT ENDPOINT (b) (4) 	19 Aug 2020 18:14:21

US3372184

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:01:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:46:36

US3372184

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered '19 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	19 Aug 2020 18:14:22

US3372184

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:46:36

US3372184

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:01:38

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	19 Aug 2020 19:46:36

US3372184

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered (b) (6) 1947'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	19 Aug 2020 18:14:23

US3372184

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:38

[Age](#)

Audit	User	Time (GMT)
User entered '72'	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:47:03

US3372184

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:38

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	19 Aug 2020 19:47:03

US3372184

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:38

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '72'	System	19 Aug 2020 19:47:16

US3372184

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:38

Sex

Audit	User	Time (GMT)
User entered 'Male (M)'	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:47:03

US3372184

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:38

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:47:03

US3372184

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:38

White

Audit	User	Time (GMT)
User entered '1'	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:47:03

US3372184

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:38

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:47:03

US3372184

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:38

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:47:03

US3372184

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:38

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:47:03

US3372184

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:38

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:47:03

US3372184

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:38

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:47:03

US3372184

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:38

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:47:03

US3372184

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:38

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:47:03

US3372184

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:01:38

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:47:03

US3372184

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered '19 Aug 2020'	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:47:16

US3372184

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	19 Aug 2020 19:47:16

US3372184

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered '2020'	System	19 Aug 2020 19:47:16

US3372184

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:38

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 2 (2)'	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:47:16

US3372184

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:47:16

US3372184

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered empty.	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:47:16

US3372184

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:38

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:47:16

US3372184

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:38

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:47:16

US3372184

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:38

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	19 Aug 2020 18:14:22

US3372184

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:01:38

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 19:47:22

US3372184

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:47:22

US3372184

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:01:38

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:36:52

US3372184

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:38

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: Gastrooesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4) (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) (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) (b) (4)	14 Oct 2020 18:46:34

US3372184

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'un UNK 2009'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:46:34

US3372184

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:46:34

US3372184

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:46:34

US3372184

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:46:34

US3372184

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:46:34

US3372184

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'Jan 2009'	System	14 Oct 2020 18:46:34

US3372184

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered '2009'	System	14 Oct 2020 18:46:34

US3372184

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 18:46:34

US3372184

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 18:46:34

US3372184

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:38

[Condition](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3372184

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'un UNK 1997'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:46:46

US3372184

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:46:46

US3372184

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:46:46

US3372184

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:38

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:46:46

US3372184

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:46:46

US3372184

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'Jan 1997'	System	14 Oct 2020 18:46:46

US3372184

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered '1997'	System	14 Oct 2020 18:46:46

US3372184

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 18:46:46

US3372184

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 18:46:46

US3372184

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:38

[Condition](#)

Audit	User	Time (GMT)
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) (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) (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) (b) (4)	14 Oct 2020 18:47:05

US3372184

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'un UNK 2019'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:47:05

US3372184

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:47:05

US3372184

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:47:05

US3372184

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:38

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:47:05

US3372184

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:47:05

US3372184

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	14 Oct 2020 18:47:05

US3372184

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered '2019'	System	14 Oct 2020 18:47:05

US3372184

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 18:47:05

US3372184

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 18:47:05

US3372184

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:38

[Condition](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3372184

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'un UNK 2019'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:47:24

US3372184

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:47:24

US3372184

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:47:24

US3372184

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:38

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:47:24

US3372184

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:47:24

US3372184

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	14 Oct 2020 18:47:24

US3372184

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered '2019'	System	14 Oct 2020 18:47:24

US3372184

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 18:47:24

US3372184

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 18:47:24

US3372184

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:38

[Condition](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3372184

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'un UNK 1970'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:47:37

US3372184

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:47:37

US3372184

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:47:37

US3372184

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:47:37

US3372184

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:47:37

US3372184

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'Jan 1970'	System	14 Oct 2020 18:47:37

US3372184

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered '1970'	System	14 Oct 2020 18:47:37

US3372184

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 18:47:37

US3372184

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 18:47:37

US3372184

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:01:38

[Condition](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3372184

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'un UNK 2005'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:47:47

US3372184

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:01:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:47:47

US3372184

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:01:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:47:47

US3372184

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:47:47

US3372184

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:01:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:47:47

US3372184

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	14 Oct 2020 18:47:47

US3372184

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered '2005'	System	14 Oct 2020 18:47:47

US3372184

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 18:47:47

US3372184

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 18:47:47

US3372184

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:01:38

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: 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
	(b) (4)	

US3372184

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'un UNK 1974'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:47:55

US3372184

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:01:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:47:55

US3372184

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:01:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:47:55

US3372184

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:01:38

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:47:55

US3372184

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:01:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:47:55

US3372184

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'Jan 1974'	System	14 Oct 2020 18:47:55

US3372184

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered '1974'	System	14 Oct 2020 18:47:55

US3372184

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 18:47:55

US3372184

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 18:47:55

US3372184

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:01:38

[Condition](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3372184

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'un UNK 1994'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:48:04

US3372184

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:01:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:48:04

US3372184

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:01:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:48:04

US3372184

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:48:04

US3372184

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:01:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:48:04

US3372184

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'Jan 1994'	System	14 Oct 2020 18:48:04

US3372184

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered '1994'	System	14 Oct 2020 18:48:04

US3372184

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 18:48:04

US3372184

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 18:48:04

US3372184

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:01:38

[Condition](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3372184

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'un UNK 1994'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:48:20

US3372184

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:01:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:48:20

US3372184

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:01:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:48:20

US3372184

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:48:20

US3372184

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:01:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:48:20

US3372184

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'Jan 1994'	System	14 Oct 2020 18:48:20

US3372184

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered '1994'	System	14 Oct 2020 18:48:20

US3372184

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 18:48:20

US3372184

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 18:48:20

US3372184

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:01:38

[Condition](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3372184

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'un UNK 1958'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:48:29

US3372184

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:01:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:48:29

US3372184

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:01:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:48:29

US3372184

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:48:29

US3372184

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:01:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:48:29

US3372184

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'Jan 1958'	System	14 Oct 2020 18:48:29

US3372184

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered '1958'	System	14 Oct 2020 18:48:29

US3372184

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 18:48:29

US3372184

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 18:48:29

US3372184

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:01:38

[Condition](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3372184

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'un UNK 1999'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:48:41

US3372184

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:01:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:48:41

US3372184

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:01:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:48:41

US3372184

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:01:38

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:48:41

US3372184

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:01:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:48:41

US3372184

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'Jan 1999'	System	14 Oct 2020 18:48:41

US3372184

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered '1999'	System	14 Oct 2020 18:48:41

US3372184

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 18:48:41

US3372184

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 18:48:41

US3372184

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:01:38

[Condition](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3372184

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'un UNK 1995'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:48:53

US3372184

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:01:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:48:53

US3372184

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:01:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:48:53

US3372184

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:48:53

US3372184

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:01:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:48:53

US3372184

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'Jan 1995'	System	14 Oct 2020 18:48:53

US3372184

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered '1995'	System	14 Oct 2020 18:48:53

US3372184

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 18:48:53

US3372184

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 18:48:53

US3372184

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:01:38

[Condition](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3372184

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'un UNK 2019'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:49:05

US3372184

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:01:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:49:05

US3372184

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:01:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:49:05

US3372184

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:01:38

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:49:05

US3372184

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:01:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:49:05

US3372184

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	14 Oct 2020 18:49:05

US3372184

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered '2019'	System	14 Oct 2020 18:49:05

US3372184

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 18:49:05

US3372184

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 18:49:05

US3372184

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:01:38

[Condition](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3372184

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'un UNK 1999'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:49:22

US3372184

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:01:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:49:22

US3372184

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:01:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:49:22

US3372184

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:01:38

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:49:22

US3372184

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:01:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:49:22

US3372184

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'Jan 1999'	System	14 Oct 2020 18:49:22

US3372184

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered '1999'	System	14 Oct 2020 18:49:22

US3372184

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 18:49:22

US3372184

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 18:49:22

US3372184

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:01:38

[Condition](#)

Audit	User	Time (GMT)
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) (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) (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) (b) (4)	14 Oct 2020 18:49:37

US3372184

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'un UNK 2017'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:49:37

US3372184

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:01:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:49:37

US3372184

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:01:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:49:37

US3372184

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:01:38

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:49:37

US3372184

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:01:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:49:37

US3372184

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	14 Oct 2020 18:49:37

US3372184

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered '2017'	System	14 Oct 2020 18:49:37

US3372184

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 18:49:37

US3372184

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 18:49:37

US3372184

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:01:38

[Condition](#)

Audit	User	Time (GMT)
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.	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.	(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: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'un UNK 2013'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:49:56

US3372184

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:01:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:49:56

US3372184

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:01:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:49:56

US3372184

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'un UNK 2013'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:49:56

US3372184

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:01:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:49:56

US3372184

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'Jan 2013'	System	14 Oct 2020 18:49:56

US3372184

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered '2013'	System	14 Oct 2020 18:49:56

US3372184

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'Jan 2013'	System	14 Oct 2020 18:49:56

US3372184

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered '2013'	System	14 Oct 2020 18:49:56

US3372184

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:01:38

[Condition](#)

Audit	User	Time (GMT)
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) (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) (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) (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) (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) (b) (4)	14 Oct 2020 18:50:52

US3372184

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'un UNK 2013'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:50:52

US3372184

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:01:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:50:52

US3372184

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:01:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:50:52

US3372184

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'un UNK 2013'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:50:52

US3372184

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:01:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:50:52

US3372184

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'Jan 2013'	System	14 Oct 2020 18:50:52

US3372184

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered '2013'	System	14 Oct 2020 18:50:52

US3372184

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'Jan 2013'	System	14 Oct 2020 18:50:52

US3372184

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered '2013'	System	14 Oct 2020 18:50:52

US3372184

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:01:38

[Condition](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3372184

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'un UNK 2007'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:51:08

US3372184

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:01:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:51:08

US3372184

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:01:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:51:08

US3372184

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'un UNK 2007'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:51:08

US3372184

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:01:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:51:08

US3372184

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'Jan 2007'	System	14 Oct 2020 18:51:08

US3372184

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered '2007'	System	14 Oct 2020 18:51:08

US3372184

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'Jan 2007'	System	14 Oct 2020 18:51:08

US3372184

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered '2007'	System	14 Oct 2020 18:51:08

US3372184

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 11:01:38

[Condition](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3372184

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'un UNK 2007'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:51:24

US3372184

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 11:01:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:51:24

US3372184

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 11:01:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:51:24

US3372184

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'un UNK 2007'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:51:24

US3372184

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 11:01:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:51:24

US3372184

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'Jan 2007'	System	14 Oct 2020 18:51:24

US3372184

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered '2007'	System	14 Oct 2020 18:51:24

US3372184

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'Jan 2007'	System	14 Oct 2020 18:51:24

US3372184

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered '2007'	System	14 Oct 2020 18:51:24

US3372184

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 11:01:38

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: 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
	(b) (4)	

US3372184

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'un UNK 2005'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:52:11

US3372184

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 11:01:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:52:11

US3372184

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 11:01:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:52:11

US3372184

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'un UNK 2005'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:52:11

US3372184

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 11:01:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:52:11

US3372184

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	14 Oct 2020 18:52:11

US3372184

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered '2005'	System	14 Oct 2020 18:52:11

US3372184

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	14 Oct 2020 18:52:11

US3372184

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered '2005'	System	14 Oct 2020 18:52:11

US3372184

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 11:01:38

[Condition](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3372184

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'un UNK 2005'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:52:28

US3372184

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 11:01:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:52:28

US3372184

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 11:01:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:52:28

US3372184

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'un UNK 2005'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:52:28

US3372184

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 11:01:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:52:28

US3372184

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	14 Oct 2020 18:52:28

US3372184

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered '2005'	System	14 Oct 2020 18:52:28

US3372184

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	14 Oct 2020 18:52:28

US3372184

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered '2005'	System	14 Oct 2020 18:52:28

US3372184

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	27 Aug 2020 17:21:18

US3372184

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:38

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020'	Peter Jacob (b) (4) (b) (4)	27 Aug 2020 17:21:18

US3372184

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:38

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '15:00'	Peter Jacob (b) (4) (b) (4)	27 Aug 2020 17:21:18

US3372184

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 15:00'	System	27 Aug 2020 17:21:18

US3372184

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:38

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered '162.6' cm	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: 26 Nov 2020 11:01:38

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered '59.6' kg	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: 26 Nov 2020 11:01:38

BMI (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[BMI units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

Temperature (xxx.x)

Audit	User	Time (GMT)
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) (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
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: 26 Nov 2020 11:01:38

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Peter Jacob (b) (4)	25 Sep 2020 17:36:40
User entered 'Oral (Oral)'	Peter Jacob (b) (4)	27 Aug 2020 17:21:18

US3372184

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:38

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	27 Aug 2020 17:21:18

US3372184

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4)	25 Sep 2020 17:36:40
User entered '52'	Peter Jacob (b) (4)	27 Aug 2020 17:21:18

US3372184

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:38

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	27 Aug 2020 17:21:18

US3372184

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4)	25 Sep 2020 17:36:40
User entered '18'	Peter Jacob (b) (4)	27 Aug 2020 17:21:18

US3372184

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	27 Aug 2020 17:21:18

US3372184

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4)	25 Sep 2020 17:36:40
User entered '152'	Peter Jacob (b) (4)	27 Aug 2020 17:21:18

US3372184

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	27 Aug 2020 17:21:18

US3372184

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:38

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4)	25 Sep 2020 17:36:40
User entered '88'	Peter Jacob (b) (4)	27 Aug 2020 17:21:18

US3372184

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	27 Aug 2020 17:21:18

US3372184

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	27 Aug 2020 17:21:25

US3372184

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '19 Aug 2020'	Peter Jacob (b) (4) (b) (4)	27 Aug 2020 17:21:25

US3372184

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:38

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:10

US3372184

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:38

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:10

US3372184

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:38

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
User entered 'No (N)'	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:10

US3372184

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:38

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
User entered 'No (N)'	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:10

US3372184

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:38

[Warehouse shipping and fulfillment centers](#) and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
User entered 'No (N)'	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:10

US3372184

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:38

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:10

US3372184

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:38

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
User entered 'No (N)'	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:10

US3372184

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:38

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
User entered 'No (N)'	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:10

US3372184

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:38

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
User entered 'No (N)'	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:10

US3372184

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:38

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:10

US3372184

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:38

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
User entered 'No (N)'	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:10

US3372184

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:38

[Other](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:10

US3372184

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:38

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:10

US3372184

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:38

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:10

US3372184

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:38

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
User entered '0'	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:10

US3372184

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:38

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
User entered '0'	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:10

US3372184

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:38

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
User entered '1'	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:10

US3372184

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:38

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
User entered '0'	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:10

US3372184

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:38

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
User entered '0'	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:10

US3372184

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:38

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:10

US3372184

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:01:38

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:10

US3372184

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:01:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:22

US3372184

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered '19 Aug 2020'	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:22

US3372184

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:22

US3372184

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:01:38

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	19 Aug 2020 19:48:22

US3372184

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:38

What was the date of randomization? (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '19 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	19 Aug 2020 19:40:31

US3372184

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:38

What was the participant's randomization number?

Audit	User	Time (GMT)
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	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) [REDACTED]	19 Aug 2020 19:40:31

US3372184

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:38

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) 	19 Aug 2020 19:40:31

US3372184

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:38

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
User entered 'No (N)'	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:48

US3372184

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:38

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
User entered 'No (N)'	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:48

US3372184

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:38

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
User entered 'No (N)'	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:48

US3372184

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:38

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:48

US3372184

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:38

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:48:48

US3372184

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:01:38

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4)	14 Oct 2020 18:54:06
Amendment Manager: DataPoint set to visible.	(b) (4)	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: 26 Nov 2020 11:01:38

Height

Audit	User	Time (GMT)
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) (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)	29 Sep 2020 15:15:40
answered with 'data updated' (Site from DM).	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4)	29 Sep 2020 15:15:13
	(b) (4)	
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)	27 Aug 2020 17:22:57
	(b) (4)	

US3372184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:01:38

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4)	29 Sep 2020 15:15:13
User entered '59.6' kg	Peter Jacob (b) (4)	27 Aug 2020 17:22:57

US3372184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:01:38

Height

Audit	User	Time (GMT)
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) (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)	29 Sep 2020 15:15:40
answered with 'data updated' (Site from DM).	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4)	29 Sep 2020 15:15:13
	(b) (4)	
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)	27 Aug 2020 17:22:57
	(b) (4)	

US3372184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:01:38

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4)	29 Sep 2020 15:15:13
User entered '59.6' kg	Peter Jacob (b) (4)	27 Aug 2020 17:22:57

US3372184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:38

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:01:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '19 Aug 2020'	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: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered '15:00'	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: 26 Nov 2020 11:01:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.4' C	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: 26 Nov 2020 11:01:38

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	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: 26 Nov 2020 11:01:38

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '52'	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: 26 Nov 2020 11:01:38

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	27 Aug 2020 17:22:57

US3372184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '18'	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: 26 Nov 2020 11:01:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	27 Aug 2020 17:22:57

US3372184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '152'	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: 26 Nov 2020 11:01:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	27 Aug 2020 17:22:57

US3372184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:38

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '88'	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: 26 Nov 2020 11:01:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	27 Aug 2020 17:22:57

US3372184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:01:38

Height

Audit	User	Time (GMT)
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) (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)	29 Sep 2020 15:15:40
answered with 'data updated' (Site from DM).	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4)	29 Sep 2020 15:15:13
	(b) (4)	
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)	27 Aug 2020 17:22:57
	(b) (4)	

US3372184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:01:38

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	Peter Jacob (b) (4)	29 Sep 2020 15:15:13
User entered '59.6' kg	Peter Jacob (b) (4)	27 Aug 2020 17:22:57

US3372184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:38

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:01:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '19 Aug 2020'	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: 26 Nov 2020 11:01:38

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '16:40'	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: 26 Nov 2020 11:01:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.1' C	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: 26 Nov 2020 11:01:38

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	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: 26 Nov 2020 11:01:38

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '48'	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: 26 Nov 2020 11:01:38

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	27 Aug 2020 17:23:51

US3372184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '18'	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: 26 Nov 2020 11:01:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	27 Aug 2020 17:23:51

US3372184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '126'	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: 26 Nov 2020 11:01:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	27 Aug 2020 17:23:51

US3372184

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:38

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '82'	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: 26 Nov 2020 11:01:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	27 Aug 2020 17:23:51

US3372184

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	27 Aug 2020 17:23:57

US3372184

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:38

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '19 Aug 2020'	Peter Jacob (b) (4) (b) (4)	27 Aug 2020 17:23:57

US3372184

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kimarie Lee-Russell (b) (4)	19 Aug 2020 20:11:22

US3372184

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:38

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Kimarie Lee-Russell (b) (4)	19 Aug 2020 20:11:22

US3372184

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered empty.	Kimarie Lee-Russell (b) (4)	19 Aug 2020 20:11:22

US3372184

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:38

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	19 Aug 2020 20:11:22

US3372184

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '19 Aug 2020'	Kimarie Lee-Russell (b) (4)	19 Aug 2020 20:11:22

US3372184

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:38

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '16:09'	Kimarie Lee-Russell (b) (4)	19 Aug 2020 20:11:22

US3372184

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:38

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 16:09'	System	19 Aug 2020 20:11:22

US3372184

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:38

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User entered 'Right Arm (RIGHT ARM)'	Kimarie Lee-Russell (b) (4)	19 Aug 2020 20:11:22

US3372184

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:38

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	19 Aug 2020 20:11:22

US3372184

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:01:38

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	19 Aug 2020 20:11:22

US3372184

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:49:47

US3372184

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '19 Aug 2020'	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:49:47

US3372184

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:38

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '15:35'	Kimarie Lee-Russell (b) (4)	19 Aug 2020 19:49:47

US3372184

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '19 Aug 2020'	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: 26 Nov 2020 11:01:38

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:01:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '15:32'	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: 26 Nov 2020 11:01:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 11:01:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 19:49:31

US3372184

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:01:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	27 Aug 2020 17:24:00

US3372184

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:01:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 17:24:00

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	19 Aug 2020 20:49:42
User entered 'Yes (Y)'	System	19 Aug 2020 20:49:42

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	19 Aug 2020 20:49:42
User entered '97.0'	System	19 Aug 2020 20:49:42

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	20 Aug 2020 09:50:37
User entered 'Yes (Y)'	System	20 Aug 2020 09:50:37

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	20 Aug 2020 09:50:37
User entered '97.5'	System	20 Aug 2020 09:50:37

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	20 Aug 2020 21:06:27
User entered 'Yes (Y)'	System	20 Aug 2020 21:06:27

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	20 Aug 2020 21:06:27
User entered '97.5'	System	20 Aug 2020 21:06:27

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	20 Aug 2020 21:06:27
User entered '20 Aug 2020 17:06'	System	20 Aug 2020 21:06:27

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	21 Aug 2020 16:26:58
User entered 'Yes (Y)'	System	21 Aug 2020 16:26:58

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	21 Aug 2020 16:26:58
User entered '97.9'	System	21 Aug 2020 16:26:58

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	21 Aug 2020 16:26:58
User entered '21 Aug 2020 12:26'	System	21 Aug 2020 16:26:58

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[TIMEPOINT](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	22 Aug 2020 16:53:26
User entered 'Yes (Y)'	System	22 Aug 2020 16:53:26

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	22 Aug 2020 16:53:26
User entered '97.2'	System	22 Aug 2020 16:53:26

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	22 Aug 2020 16:53:26
User entered '22 Aug 2020 12:53'	System	22 Aug 2020 16:53:26

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	23 Aug 2020 16:08:39
User entered 'Yes (Y)'	System	23 Aug 2020 16:08:39

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	23 Aug 2020 16:08:39
User entered '97.9'	System	23 Aug 2020 16:08:39

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	23 Aug 2020 16:08:39
User entered '23 Aug 2020 12:08'	System	23 Aug 2020 16:08:39

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[TIMEPOINT](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	24 Aug 2020 17:26:22
User entered 'Yes (Y)'	System	24 Aug 2020 17:26:22

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	24 Aug 2020 17:26:22
User entered '98.1'	System	24 Aug 2020 17:26:22

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	24 Aug 2020 17:26:22
User entered '24 Aug 2020 13:26'	System	24 Aug 2020 17:26:22

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	25 Aug 2020 16:10:17
User entered 'Yes (Y)'	System	25 Aug 2020 16:10:17

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	25 Aug 2020 16:10:17
User entered '98.0'	System	25 Aug 2020 16:10:17

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	25 Aug 2020 16:10:17
User entered '25 Aug 2020 12:10'	System	25 Aug 2020 16:10:17

US3372184

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

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

Please select one response below

Audit	User	Time (GMT)
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'	System	20 Aug 2020 09:51:19
User entered 'None (1)'	System	20 Aug 2020 09:51:19

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	20 Aug 2020 09:51:19
User entered 'No (N)'	System	20 Aug 2020 09:51:19

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
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'	System	20 Aug 2020 09:51:19
User entered 'No (N)'	System	20 Aug 2020 09:51:19

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:38

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

Please select one response below

Audit	User	Time (GMT)
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'	System	20 Aug 2020 09:51:19
User entered 'None (1)'	System	20 Aug 2020 09:51:19

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	20 Aug 2020 09:51:19
User entered '20 Aug 2020 05:51'	System	20 Aug 2020 09:51:19

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
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'	System	20 Aug 2020 21:06:51
User entered 'No (N)'	System	20 Aug 2020 21:06:51

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
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'	System	20 Aug 2020 21:06:51
User entered 'No (N)'	System	20 Aug 2020 21:06:51

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:38

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	20 Aug 2020 21:06:51
User entered '20 Aug 2020 17:06'	System	20 Aug 2020 21:06:51

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

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

Please select one response below

Audit	User	Time (GMT)
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'	System	21 Aug 2020 16:28:00
User entered 'None (1)'	System	21 Aug 2020 16:28:00

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	21 Aug 2020 16:28:00
User entered 'No (N)'	System	21 Aug 2020 16:28:00

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
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'	System	21 Aug 2020 16:28:00
User entered 'No (N)'	System	21 Aug 2020 16:28:00

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:38

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

Please select one response below

Audit	User	Time (GMT)
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'	System	21 Aug 2020 16:28:00
User entered 'None (1)'	System	21 Aug 2020 16:28:00

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	21 Aug 2020 16:28:00
User entered '21 Aug 2020 12:27'	System	21 Aug 2020 16:28:00

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

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

Please select one response below

Audit	User	Time (GMT)
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'	System	22 Aug 2020 16:53:49
User entered 'None (1)'	System	22 Aug 2020 16:53:49

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	22 Aug 2020 16:53:49
User entered 'No (N)'	System	22 Aug 2020 16:53:49

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
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'	System	22 Aug 2020 16:53:49
User entered 'No (N)'	System	22 Aug 2020 16:53:49

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:38

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

Please select one response below

Audit	User	Time (GMT)
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'	System	22 Aug 2020 16:53:49
User entered 'None (1)'	System	22 Aug 2020 16:53:49

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	22 Aug 2020 16:53:49
User entered '22 Aug 2020 12:53'	System	22 Aug 2020 16:53:49

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	24 Aug 2020 17:26:41
User entered 'No (N)'	System	24 Aug 2020 17:26:41

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
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'	System	24 Aug 2020 17:26:41
User entered 'No (N)'	System	24 Aug 2020 17:26:41

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:38

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

Please select one response below

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 11:01:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	24 Aug 2020 17:26:41
User entered '24 Aug 2020 13:26'	System	24 Aug 2020 17:26:41

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	25 Aug 2020 16:10:51
User entered 'No (N)'	System	25 Aug 2020 16:10:51

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
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'	System	25 Aug 2020 16:10:51
User entered 'No (N)'	System	25 Aug 2020 16:10:51

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:38

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

Please select one response below

Audit	User	Time (GMT)
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'	System	25 Aug 2020 16:10:51
User entered 'None (1)'	System	25 Aug 2020 16:10:51

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	25 Aug 2020 16:10:51
User entered '25 Aug 2020 12:10'	System	25 Aug 2020 16:10:51

US3372184

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

HEADACHE

Audit	User	Time (GMT)
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'	System	19 Aug 2020 20:50:39
User entered 'None (0)'	System	19 Aug 2020 20:50:39

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:38

FATIGUE

Audit	User	Time (GMT)
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'	System	19 Aug 2020 20:50:39
User entered 'None (0)'	System	19 Aug 2020 20:50:39

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	19 Aug 2020 20:50:39
User entered 'None (0)'	System	19 Aug 2020 20:50:39

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	19 Aug 2020 20:50:39
User entered 'None (0)'	System	19 Aug 2020 20:50:39

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	19 Aug 2020 20:50:39
User entered 'None (0)'	System	19 Aug 2020 20:50:39

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:38

CHILLS

Audit	User	Time (GMT)
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'	System	19 Aug 2020 20:50:39
User entered 'None (0)'	System	19 Aug 2020 20:50:39

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
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'	System	19 Aug 2020 20:50:39
User entered 'No (N)'	System	19 Aug 2020 20:50:39

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:38

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

HEADACHE

Audit	User	Time (GMT)
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'	System	20 Aug 2020 09:52:16
User entered 'None (0)'	System	20 Aug 2020 09:52:16

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:38

FATIGUE

Audit	User	Time (GMT)
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'	System	20 Aug 2020 09:52:16
User entered 'None (0)'	System	20 Aug 2020 09:52:16

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	20 Aug 2020 09:52:16
User entered 'None (0)'	System	20 Aug 2020 09:52:16

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	20 Aug 2020 09:52:16
User entered 'None (0)'	System	20 Aug 2020 09:52:16

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	20 Aug 2020 09:52:16
User entered 'None (0)'	System	20 Aug 2020 09:52:16

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:38

CHILLS

Audit	User	Time (GMT)
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'	System	20 Aug 2020 09:52:16
User entered 'None (0)'	System	20 Aug 2020 09:52:16

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
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'	System	20 Aug 2020 09:52:16
User entered 'No (N)'	System	20 Aug 2020 09:52:16

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:38

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

HEADACHE

Audit	User	Time (GMT)
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'	System	20 Aug 2020 21:07:29
User entered 'None (0)'	System	20 Aug 2020 21:07:29

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:38

FATIGUE

Audit	User	Time (GMT)
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'	System	20 Aug 2020 21:07:29
User entered 'None (0)'	System	20 Aug 2020 21:07:29

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	20 Aug 2020 21:07:29
User entered 'None (0)'	System	20 Aug 2020 21:07:29

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	20 Aug 2020 21:07:29
User entered 'None (0)'	System	20 Aug 2020 21:07:29

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	20 Aug 2020 21:07:29
User entered 'None (0)'	System	20 Aug 2020 21:07:29

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:38

CHILLS

Audit	User	Time (GMT)
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'	System	20 Aug 2020 21:07:29
User entered 'No interference with activity (1)'	System	20 Aug 2020 21:07:29

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
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'	System	20 Aug 2020 21:07:29
User entered 'No (N)'	System	20 Aug 2020 21:07:29

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:38

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	20 Aug 2020 21:07:29
User entered '20 Aug 2020 17:07'	System	20 Aug 2020 21:07:29

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

HEADACHE

Audit	User	Time (GMT)
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'	System	21 Aug 2020 16:28:28
User entered 'None (0)'	System	21 Aug 2020 16:28:28

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:38

FATIGUE

Audit	User	Time (GMT)
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'	System	21 Aug 2020 16:28:28
User entered 'None (0)'	System	21 Aug 2020 16:28:28

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	21 Aug 2020 16:28:28
User entered 'None (0)'	System	21 Aug 2020 16:28:28

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	21 Aug 2020 16:28:28
User entered 'None (0)'	System	21 Aug 2020 16:28:28

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	21 Aug 2020 16:28:28
User entered 'None (0)'	System	21 Aug 2020 16:28:28

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:38

CHILLS

Audit	User	Time (GMT)
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'	System	21 Aug 2020 16:28:28
User entered 'None (0)'	System	21 Aug 2020 16:28:28

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
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'	System	21 Aug 2020 16:28:28
User entered 'No (N)'	System	21 Aug 2020 16:28:28

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:38

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	21 Aug 2020 16:28:28
User entered '21 Aug 2020 12:28'	System	21 Aug 2020 16:28:28

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

HEADACHE

Audit	User	Time (GMT)
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'	System	22 Aug 2020 16:54:17
User entered 'None (0)'	System	22 Aug 2020 16:54:17

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:38

FATIGUE

Audit	User	Time (GMT)
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'	System	22 Aug 2020 16:54:17
User entered 'None (0)'	System	22 Aug 2020 16:54:17

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	22 Aug 2020 16:54:17
User entered 'None (0)'	System	22 Aug 2020 16:54:17

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	22 Aug 2020 16:54:17
User entered 'None (0)'	System	22 Aug 2020 16:54:17

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	22 Aug 2020 16:54:17
User entered 'None (0)'	System	22 Aug 2020 16:54:17

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:38

CHILLS

Audit	User	Time (GMT)
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'	System	22 Aug 2020 16:54:17
User entered 'None (0)'	System	22 Aug 2020 16:54:17

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	22 Aug 2020 16:54:17
User entered '22 Aug 2020 12:54'	System	22 Aug 2020 16:54:17

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

HEADACHE

Audit	User	Time (GMT)
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'	System	23 Aug 2020 16:09:37
User entered 'None (0)'	System	23 Aug 2020 16:09:37

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:38

FATIGUE

Audit	User	Time (GMT)
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'	System	23 Aug 2020 16:09:37
User entered 'None (0)'	System	23 Aug 2020 16:09:37

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	23 Aug 2020 16:09:37
User entered 'None (0)'	System	23 Aug 2020 16:09:37

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	23 Aug 2020 16:09:37
User entered 'None (0)'	System	23 Aug 2020 16:09:37

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	23 Aug 2020 16:09:37
User entered 'None (0)'	System	23 Aug 2020 16:09:37

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:38

CHILLS

Audit	User	Time (GMT)
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'	System	23 Aug 2020 16:09:37
User entered 'None (0)'	System	23 Aug 2020 16:09:37

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
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'	System	23 Aug 2020 16:09:37
User entered 'No (N)'	System	23 Aug 2020 16:09:37

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:38

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	23 Aug 2020 16:09:37
User entered '23 Aug 2020 12:09'	System	23 Aug 2020 16:09:37

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

HEADACHE

Audit	User	Time (GMT)
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'	System	24 Aug 2020 17:27:09
User entered 'None (0)'	System	24 Aug 2020 17:27:09

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:38

FATIGUE

Audit	User	Time (GMT)
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'	System	24 Aug 2020 17:27:09
User entered 'None (0)'	System	24 Aug 2020 17:27:09

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	24 Aug 2020 17:27:09
User entered 'None (0)'	System	24 Aug 2020 17:27:09

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	24 Aug 2020 17:27:09
User entered 'None (0)'	System	24 Aug 2020 17:27:09

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	24 Aug 2020 17:27:09
User entered 'None (0)'	System	24 Aug 2020 17:27:09

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:38

CHILLS

Audit	User	Time (GMT)
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'	System	24 Aug 2020 17:27:09
User entered 'None (0)'	System	24 Aug 2020 17:27:09

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
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'	System	24 Aug 2020 17:27:09
User entered 'No (N)'	System	24 Aug 2020 17:27:09

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:38

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	24 Aug 2020 17:27:09
User entered '24 Aug 2020 13:27'	System	24 Aug 2020 17:27:09

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

HEADACHE

Audit	User	Time (GMT)
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'	System	25 Aug 2020 16:11:15
User entered 'None (0)'	System	25 Aug 2020 16:11:15

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:38

FATIGUE

Audit	User	Time (GMT)
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'	System	25 Aug 2020 16:11:15
User entered 'None (0)'	System	25 Aug 2020 16:11:15

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	25 Aug 2020 16:11:15
User entered 'None (0)'	System	25 Aug 2020 16:11:15

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	25 Aug 2020 16:11:15
User entered 'None (0)'	System	25 Aug 2020 16:11:15

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	25 Aug 2020 16:11:15
User entered 'None (0)'	System	25 Aug 2020 16:11:15

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:38

CHILLS

Audit	User	Time (GMT)
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'	System	25 Aug 2020 16:11:15
User entered 'None (0)'	System	25 Aug 2020 16:11:15

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
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'	System	25 Aug 2020 16:11:15
User entered 'No (N)'	System	25 Aug 2020 16:11:15

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:38

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	25 Aug 2020 16:11:15
User entered '25 Aug 2020 12:11'	System	25 Aug 2020 16:11:15

US3372184

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alexandra Arango (b) (4) (b) (4)	27 Aug 2020 20:01:12

US3372184

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:38

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020'	Alexandra Arango (b) (4) (b) (4)	27 Aug 2020 20:01:12

US3372184

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Alexandra Arango (b) (4) (b) (4)	27 Aug 2020 20:01:12

US3372184

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Alexandra Arango (b) (4) (b) (4)	27 Aug 2020 20:01:12

US3372184

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alexandra Arango (b) (4) (b) (4)	27 Aug 2020 20:01:17

US3372184

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 20:01:17

US3372184

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alexandra Arango (b) (4) (b) (4)	04 Sep 2020 20:03:51

US3372184

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:38

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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)	04 Sep 2020 20:03:51
	(b) (4)	

US3372184

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Alexandra Arango (b) (4) (b) (4)	04 Sep 2020 20:03:51

US3372184

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Alexandra Arango (b) (4) (b) (4)	04 Sep 2020 20:03:51

US3372184

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alexandra Arango (b) (4) (b) (4)	04 Sep 2020 20:03:54

US3372184

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 20:03:54

US3372184

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alexandra Arango (b) (4) (b) (4)	09 Sep 2020 18:20:56

US3372184

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:38

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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)	09 Sep 2020 18:20:56
	(b) (4)	

US3372184

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Alexandra Arango (b) (4) (b) (4)	09 Sep 2020 18:20:56

US3372184

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Alexandra Arango (b) (4) (b) (4)	09 Sep 2020 18:20:56

US3372184

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alexandra Arango (b) (4) (b) (4)	09 Sep 2020 18:22:00

US3372184

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 18:22:00

US3372184

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:01:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 18:57:07

US3372184

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered '22 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 18:57:07

US3372184

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	22 Sep 2020 18:57:07

US3372184

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:01:38

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	22 Sep 2020 18:57:07

US3372184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:38

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:01:38

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020'	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: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered '14:35'	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: 26 Nov 2020 11:01:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.6' C	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: 26 Nov 2020 11:01:38

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	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: 26 Nov 2020 11:01:38

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '54'	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: 26 Nov 2020 11:01:38

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	24 Sep 2020 23:15:08

US3372184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '16'	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: 26 Nov 2020 11:01:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '160'	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: 26 Nov 2020 11:01:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Sep 2020 23:15:08

US3372184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:01:38

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '81'	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: 26 Nov 2020 11:01:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Sep 2020 23:15:08

US3372184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:38

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:01:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '22 Sep 2020'	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: 26 Nov 2020 11:01:38

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '16:21'	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: 26 Nov 2020 11:01:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

Temperature (xxx.x)

Audit	User	Time (GMT)
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) (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.'	Peter Jacob (b) (4)	24 Sep 2020 23:16:01
answered with 'ncs' (Site from System).	(b) (4)	
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)	24 Sep 2020 23:15:53
	(b) (4)	

US3372184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:38

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	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: 26 Nov 2020 11:01:38

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '45'	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: 26 Nov 2020 11:01:38

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	24 Sep 2020 23:15:53

US3372184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '16'	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: 26 Nov 2020 11:01:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '164'	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: 26 Nov 2020 11:01:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Sep 2020 23:15:53

US3372184

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:01:38

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '79'	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: 26 Nov 2020 11:01:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Sep 2020 23:15:53

US3372184

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	24 Sep 2020 23:16:13

US3372184

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:38

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '22 Sep 2020'	Peter Jacob (b) (4) (b) (4)	24 Sep 2020 23:16:13

US3372184

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:01:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 19:50:15

US3372184

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:01:38

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 19:50:15

US3372184

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 19:50:15

US3372184

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:01:38

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	22 Sep 2020 19:50:15

US3372184

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:01:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '22 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 19:50:15

US3372184

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:01:38

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '15:42'	(b) (4), (b) (6)	22 Sep 2020 19:50:15

US3372184

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:01:38

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User entered 'Right Arm (RIGHT ARM)'	(b) (4), (b) (6)	22 Sep 2020 19:50:15

US3372184

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:01:38

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	22 Sep 2020 19:50:15

US3372184

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:01:38

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	22 Sep 2020 19:50:15

US3372184

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	24 Sep 2020 23:16:21

US3372184

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered '22 Sep 2020'	Peter Jacob (b) (4) (b) (4)	24 Sep 2020 23:16:21

US3372184

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:38

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '15:03'	Peter Jacob (b) (4) (b) (4)	24 Sep 2020 23:16:21

US3372184

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '22 Sep 2020'	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: 26 Nov 2020 11:01:38

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:01:38

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered '14:59'	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: 26 Nov 2020 11:01:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 11:01:38

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 23:16:34

US3372184

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	24 Sep 2020 23:16:39

US3372184

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 23:16:39

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	22 Sep 2020 20:22:09
User entered 'Yes (Y)'	System	22 Sep 2020 20:22:09

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	22 Sep 2020 20:22:09
User entered '96.5'	System	22 Sep 2020 20:22:09

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
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'	System	22 Sep 2020 20:22:09
User entered 'No (N)'	System	22 Sep 2020 20:22:09

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	22 Sep 2020 20:22:09
User entered '22 Sep 2020 16:22'	System	22 Sep 2020 20:22:09

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:01:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	23 Sep 2020 09:27:47
User entered 'Yes (Y)'	System	23 Sep 2020 09:27:47

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	23 Sep 2020 09:27:47
User entered '98.0'	System	23 Sep 2020 09:27:47

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
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'	System	23 Sep 2020 09:27:47
User entered 'No (N)'	System	23 Sep 2020 09:27:47

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	23 Sep 2020 09:27:47
User entered '23 Sep 2020 05:27'	System	23 Sep 2020 09:27:47

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:01:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	24 Sep 2020 09:25:49
User entered 'Yes (Y)'	System	24 Sep 2020 09:25:49

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
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'	System	24 Sep 2020 09:25:49
User entered 'No (N)'	System	24 Sep 2020 09:25:49

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:01:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	25 Sep 2020 12:24:21
User entered '97.2'	System	25 Sep 2020 12:24:21

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	25 Sep 2020 12:24:21
User entered '25 Sep 2020 08:24'	System	25 Sep 2020 12:24:21

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:01:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	26 Sep 2020 09:59:41
User entered 'Yes (Y)'	System	26 Sep 2020 09:59:41

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	26 Sep 2020 09:59:41
User entered '97.2'	System	26 Sep 2020 09:59:41

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	26 Sep 2020 09:59:41
User entered '26 Sep 2020 05:59'	System	26 Sep 2020 09:59:41

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:01:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	27 Sep 2020 10:39:08
User entered '97.4'	System	27 Sep 2020 10:39:08

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
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'	System	27 Sep 2020 10:39:08
User entered 'No (N)'	System	27 Sep 2020 10:39:08

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	27 Sep 2020 10:39:08
User entered '27 Sep 2020 06:39'	System	27 Sep 2020 10:39:08

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:01:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	28 Sep 2020 11:53:07
User entered 'Yes (Y)'	System	28 Sep 2020 11:53:07

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
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'	System	28 Sep 2020 11:53:07
User entered 'No (N)'	System	28 Sep 2020 11:53:07

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	28 Sep 2020 11:53:07
User entered '28 Sep 2020 07:53'	System	28 Sep 2020 11:53:07

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:01:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	29 Sep 2020 15:21:46
User entered 'Yes (Y)'	System	29 Sep 2020 15:21:46

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	29 Sep 2020 15:21:46
User entered '97.7'	System	29 Sep 2020 15:21:46

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	29 Sep 2020 15:21:46
User entered '29 Sep 2020 11:21'	System	29 Sep 2020 15:21:46

US3372184

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:01:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	22 Sep 2020 20:22:41
User entered 'No (N)'	System	22 Sep 2020 20:22:41

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
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'	System	22 Sep 2020 20:22:41
User entered 'No (N)'	System	22 Sep 2020 20:22:41

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:38

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	22 Sep 2020 20:22:41
User entered '22 Sep 2020 16:22'	System	22 Sep 2020 20:22:41

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:01:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

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

Please select one response below

Audit	User	Time (GMT)
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'	System	23 Sep 2020 09:28:57
User entered 'None (1)'	System	23 Sep 2020 09:28:57

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	23 Sep 2020 09:28:57
User entered 'No (N)'	System	23 Sep 2020 09:28:57

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
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'	System	23 Sep 2020 09:28:57
User entered 'No (N)'	System	23 Sep 2020 09:28:57

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:38

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

Please select one response below

Audit	User	Time (GMT)
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'	System	23 Sep 2020 09:28:57
User entered 'None (1)'	System	23 Sep 2020 09:28:57

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	23 Sep 2020 09:28:57
User entered '23 Sep 2020 05:28'	System	23 Sep 2020 09:28:57

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:01:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	24 Sep 2020 09:26:18
User entered '24 Sep 2020 05:26'	System	24 Sep 2020 09:26:18

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:01:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

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

Please select one response below

Audit	User	Time (GMT)
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'	System	25 Sep 2020 12:24:41
User entered 'None (1)'	System	25 Sep 2020 12:24:41

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	25 Sep 2020 12:24:41
User entered 'No (N)'	System	25 Sep 2020 12:24:41

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
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'	System	25 Sep 2020 12:24:41
User entered 'No (N)'	System	25 Sep 2020 12:24:41

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:38

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

Please select one response below

Audit	User	Time (GMT)
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'	System	25 Sep 2020 12:24:41
User entered 'None (1)'	System	25 Sep 2020 12:24:41

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:01:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	26 Sep 2020 10:00:08
User entered 'No (N)'	System	26 Sep 2020 10:00:08

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
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'	System	26 Sep 2020 10:00:08
User entered 'No (N)'	System	26 Sep 2020 10:00:08

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:01:38

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	27 Sep 2020 10:39:29
User entered 'No (N)'	System	27 Sep 2020 10:39:29

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
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'	System	27 Sep 2020 10:39:29
User entered 'No (N)'	System	27 Sep 2020 10:39:29

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:38

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	27 Sep 2020 10:39:29
User entered '27 Sep 2020 06:39'	System	27 Sep 2020 10:39:29

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:01:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

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

Please select one response below

Audit	User	Time (GMT)
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'	System	28 Sep 2020 11:56:52
User entered 'None (1)'	System	28 Sep 2020 11:56:52

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	28 Sep 2020 11:56:52
User entered 'No (N)'	System	28 Sep 2020 11:56:52

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
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'	System	28 Sep 2020 11:56:52
User entered 'No (N)'	System	28 Sep 2020 11:56:52

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:38

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

Please select one response below

Audit	User	Time (GMT)
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'	System	28 Sep 2020 11:56:52
User entered 'None (1)'	System	28 Sep 2020 11:56:52

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	28 Sep 2020 11:56:52
User entered '28 Sep 2020 07:56'	System	28 Sep 2020 11:56:52

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:01:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 11:01:38

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	29 Sep 2020 15:22:02
User entered '29 Sep 2020 11:22'	System	29 Sep 2020 15:22:02

US3372184

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:01:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

HEADACHE

Audit	User	Time (GMT)
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'	System	22 Sep 2020 20:23:27
User entered 'None (0)'	System	22 Sep 2020 20:23:27

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:38

FATIGUE

Audit	User	Time (GMT)
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

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	22 Sep 2020 20:23:27
User entered 'None (0)'	System	22 Sep 2020 20:23:27

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:38

CHILLS

Audit	User	Time (GMT)
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'	System	22 Sep 2020 20:23:27
User entered 'None (0)'	System	22 Sep 2020 20:23:27

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
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'	System	22 Sep 2020 20:23:27
User entered 'No (N)'	System	22 Sep 2020 20:23:27

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:01:38

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

HEADACHE

Audit	User	Time (GMT)
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'	System	23 Sep 2020 09:29:25
User entered 'None (0)'	System	23 Sep 2020 09:29:25

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:38

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	23 Sep 2020 09:29:25
User entered 'None (0)'	System	23 Sep 2020 09:29:25

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:38

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
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'	System	23 Sep 2020 09:29:25
User entered 'No (N)'	System	23 Sep 2020 09:29:25

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:38

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	23 Sep 2020 09:29:25
User entered '23 Sep 2020 05:29'	System	23 Sep 2020 09:29:25

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:01:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

HEADACHE

Audit	User	Time (GMT)
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'	System	24 Sep 2020 09:26:38
User entered 'None (0)'	System	24 Sep 2020 09:26:38

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:38

FATIGUE

Audit	User	Time (GMT)
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'	System	24 Sep 2020 09:26:38
User entered 'None (0)'	System	24 Sep 2020 09:26:38

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	24 Sep 2020 09:26:38
User entered 'None (0)'	System	24 Sep 2020 09:26:38

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	24 Sep 2020 09:26:38
User entered 'None (0)'	System	24 Sep 2020 09:26:38

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	24 Sep 2020 09:26:38
User entered 'None (0)'	System	24 Sep 2020 09:26:38

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:38

CHILLS

Audit	User	Time (GMT)
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'	System	24 Sep 2020 09:26:38
User entered 'None (0)'	System	24 Sep 2020 09:26:38

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
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'	System	24 Sep 2020 09:26:38
User entered 'No (N)'	System	24 Sep 2020 09:26:38

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:38

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	24 Sep 2020 09:26:38
User entered '24 Sep 2020 05:26'	System	24 Sep 2020 09:26:38

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:01:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

HEADACHE

Audit	User	Time (GMT)
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'	System	25 Sep 2020 12:25:07
User entered 'None (0)'	System	25 Sep 2020 12:25:07

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:38

FATIGUE

Audit	User	Time (GMT)
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'	System	25 Sep 2020 12:25:07
User entered 'None (0)'	System	25 Sep 2020 12:25:07

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	25 Sep 2020 12:25:07
User entered 'None (0)'	System	25 Sep 2020 12:25:07

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	25 Sep 2020 12:25:07
User entered 'None (0)'	System	25 Sep 2020 12:25:07

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	25 Sep 2020 12:25:07
User entered 'None (0)'	System	25 Sep 2020 12:25:07

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:38

CHILLS

Audit	User	Time (GMT)
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'	System	25 Sep 2020 12:25:07
User entered 'None (0)'	System	25 Sep 2020 12:25:07

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
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'	System	25 Sep 2020 12:25:07
User entered 'No (N)'	System	25 Sep 2020 12:25:07

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:38

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	25 Sep 2020 12:25:07
User entered '25 Sep 2020 08:24'	System	25 Sep 2020 12:25:07

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:01:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

HEADACHE

Audit	User	Time (GMT)
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'	System	26 Sep 2020 10:00:37
User entered 'None (0)'	System	26 Sep 2020 10:00:37

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:38

FATIGUE

Audit	User	Time (GMT)
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'	System	26 Sep 2020 10:00:37
User entered 'None (0)'	System	26 Sep 2020 10:00:37

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	26 Sep 2020 10:00:37
User entered 'None (0)'	System	26 Sep 2020 10:00:37

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	26 Sep 2020 10:00:37
User entered 'None (0)'	System	26 Sep 2020 10:00:37

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	26 Sep 2020 10:00:37
User entered 'None (0)'	System	26 Sep 2020 10:00:37

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:38

CHILLS

Audit	User	Time (GMT)
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'	System	26 Sep 2020 10:00:37
User entered 'None (0)'	System	26 Sep 2020 10:00:37

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
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'	System	26 Sep 2020 10:00:37
User entered 'Yes (Y)'	System	26 Sep 2020 10:00:37

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:01:38

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

HEADACHE

Audit	User	Time (GMT)
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'	System	27 Sep 2020 10:39:50
User entered 'None (0)'	System	27 Sep 2020 10:39:50

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:38

FATIGUE

Audit	User	Time (GMT)
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'	System	27 Sep 2020 10:39:50
User entered 'None (0)'	System	27 Sep 2020 10:39:50

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	27 Sep 2020 10:39:50
User entered 'None (0)'	System	27 Sep 2020 10:39:50

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	27 Sep 2020 10:39:50
User entered 'None (0)'	System	27 Sep 2020 10:39:50

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	27 Sep 2020 10:39:50
User entered 'None (0)'	System	27 Sep 2020 10:39:50

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:38

CHILLS

Audit	User	Time (GMT)
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'	System	27 Sep 2020 10:39:50
User entered 'None (0)'	System	27 Sep 2020 10:39:50

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
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'	System	27 Sep 2020 10:39:50
User entered 'No (N)'	System	27 Sep 2020 10:39:50

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:38

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	27 Sep 2020 10:39:50
User entered '27 Sep 2020 06:39'	System	27 Sep 2020 10:39:50

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:01:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
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'	System	28 Sep 2020 11:57:23
User entered 'No (N)'	System	28 Sep 2020 11:57:23

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:01:38

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

HEADACHE

Audit	User	Time (GMT)
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'	System	29 Sep 2020 15:22:40
User entered 'None (0)'	System	29 Sep 2020 15:22:40

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:38

FATIGUE

Audit	User	Time (GMT)
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'	System	29 Sep 2020 15:22:40
User entered 'None (0)'	System	29 Sep 2020 15:22:40

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	29 Sep 2020 15:22:40
User entered 'None (0)'	System	29 Sep 2020 15:22:40

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	29 Sep 2020 15:22:40
User entered 'None (0)'	System	29 Sep 2020 15:22:40

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	29 Sep 2020 15:22:40
User entered 'None (0)'	System	29 Sep 2020 15:22:40

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:38

CHILLS

Audit	User	Time (GMT)
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'	System	29 Sep 2020 15:22:40
User entered 'None (0)'	System	29 Sep 2020 15:22:40

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
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'	System	29 Sep 2020 15:22:40
User entered 'No (N)'	System	29 Sep 2020 15:22:40

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:38

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	29 Sep 2020 15:22:40
User entered '29 Sep 2020 11:22'	System	29 Sep 2020 15:22:40

US3372184

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:01:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danielle Theodore (b) (4)	30 Sep 2020 16:50:06
	(b) (4)	
	(b) (4)	

US3372184

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
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) (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)	30 Sep 2020 16:50:06
	(b) (4)	
	(b) (4)	

US3372184

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Danielle Theodore (b) (4)	30 Sep 2020 16:50:06
	(b) (4)	
	(b) (4)	

US3372184

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Danielle Theodore (b) (4)	30 Sep 2020 16:50:06
	(b) (4)	
	(b) (4)	

US3372184

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danielle Theodore (b) (4)	30 Sep 2020 16:50:30
	(b) (4)	
	(b) (4)	

US3372184

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 16:50:30

US3372184

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danielle Theodore (b) (4)	30 Sep 2020 16:50:41
	(b) (4)	
	(b) (4)	

US3372184

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
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) (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.'	Danielle Theodore (b) (4)	06 Nov 2020 20:02:46
answered with 'visit 2 was pushed back due to lack of lab kits' (Site from System).	(b) (4)	
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)	30 Sep 2020 16:50:41
	(b) (4)	
	(b) (4)	

US3372184

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Danielle Theodore (b) (4)	30 Sep 2020 16:50:41
	(b) (4)	
	(b) (4)	

US3372184

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Danielle Theodore (b) (4)	30 Sep 2020 16:50:41
	(b) (4)	
	(b) (4)	

US3372184

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:38

Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danielle Theodore (b) (4)	30 Sep 2020 16:51:12
	(b) (4)	
	(b) (4)	

US3372184

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 16:51:12

US3372184

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alexandra Arango (b) (4) (b) (4)	07 Oct 2020 17:17:36

US3372184

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
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)	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)	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)	07 Oct 2020 17:17:36

US3372184

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Alexandra Arango (b) (4) (b) (4)	07 Oct 2020 17:17:36

US3372184

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Alexandra Arango (b) (4) (b) (4)	07 Oct 2020 17:17:36

US3372184

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Alexandra Arango (b) (4) (b) (4)	07 Oct 2020 17:17:49

US3372184

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 17:17:49

US3372184

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:01:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 18:06:24

US3372184

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User closed query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	16 Oct 2020 19:03:12
Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.'	Peter Jacob (b) (4)	14 Oct 2020 18:31:11
answered with 'per CRA window is based off of visit 1 date' (Site from System).	(b) (4)	
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: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	14 Oct 2020 18:06:24

US3372184

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:01:38

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	14 Oct 2020 18:06:24

US3372184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:32:29

US3372184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:32:29

US3372184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:38

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:32:29

US3372184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 18:32:29

US3372184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:38

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:32:29

US3372184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:38

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:32:29

US3372184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:38

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:32:29

US3372184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:32:29

US3372184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:38

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 18:32:29

US3372184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:32:29

US3372184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 18:32:29

US3372184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:32:29

US3372184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 18:32:29

US3372184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:32:29

US3372184

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:01:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 18:32:29

US3372184

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:32:51

US3372184

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:01:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:32:51

US3372184

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:33:59

US3372184

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered '14 Oct 2020'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:33:59

US3372184

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:38

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '14:14'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 18:33:59

US3372184

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:01:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 18:06:32

US3372184

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Oct 2020 18:06:32

US3372184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

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 (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: 26 Nov 2020 11:01:38

Have you been exposed to someone with 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 (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: 26 Nov 2020 11:01:38

[Date and time of submission](#)

Audit	User	Time (GMT)
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'	System	19 Oct 2020 12:43:57
User entered '19 Oct 2020 08:43:55'	System	19 Oct 2020 12:43:57

US3372184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[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 (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: 26 Nov 2020 11:01:38

Have you been exposed to someone with 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 (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: 26 Nov 2020 11:01:38

[Date and time of submission](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

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 (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-11-02T09:03:55', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '544bd50a-b9b2-446f-aefa-e5dfb086d5ca'	System	02 Nov 2020 14:04:07
User entered 'No (N)'	System	02 Nov 2020 14:04:07

US3372184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

Have you been exposed to someone with 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 (F1AAC18A-D137-44C0-B53D-0B26935D1EE2)', Time: '2020-11-02T09:04:01', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '544bd50a-b9b2-446f-aeefa-e5dfb086d5ca'	System	02 Nov 2020 14:04:07
User entered 'No (N)'	System	02 Nov 2020 14:04:07

US3372184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

[Date and time of submission](#)

Audit	User	Time (GMT)
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-aeefa-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: 26 Nov 2020 11:01:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

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: '2020-11-18T13:02:01', 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: 26 Nov 2020 11:01:38

Have you been exposed to someone with 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: '2020-11-18T13:02:08', 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: 26 Nov 2020 11:01:38

[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: '2020-11-18T13:02:12', User OID: 'PatientReportedOutcome (US3372184)', ODM File OID: '223e1578-4744-4d64-8c85-2489753c5691'	System	18 Nov 2020 18:02:15
User entered '18 Nov 2020 13:02:12'	System	18 Nov 2020 18:02:15

US3372184

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

[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 Oct 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: 26 Nov 2020 11:01:38

[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 Oct 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: 26 Nov 2020 11:01:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

[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 Oct 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: 26 Nov 2020 11:01:38

[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 Oct 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: 26 Nov 2020 11:01:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

[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 Oct 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: 26 Nov 2020 11:01:38

[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 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: 26 Nov 2020 11:01:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

[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 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: 26 Nov 2020 11:01:38

[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 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: 26 Nov 2020 11:01:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:10:58
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 23:10:58

US3372184

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:01:38

[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 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: 26 Nov 2020 11:01:38

[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 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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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'	System	23 Nov 2020 08:38:37
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: 26 Nov 2020 11:01:38

Have you been exposed to someone with 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'	System	23 Nov 2020 08:38:37
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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danielle Theodore (b) (4) (b) (4) (b) (4)	17 Nov 2020 18:08:05

US3372184

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:38

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '17 Nov 2020'	Danielle Theodore (b) (4)	17 Nov 2020 18:08:05
	(b) (4)	
	(b) (4)	

US3372184

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Danielle Theodore (b) (4)	17 Nov 2020 18:08:05
	(b) (4)	
	(b) (4)	

US3372184

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:01:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Danielle Theodore (b) (4)	17 Nov 2020 18:08:05
	(b) (4)	
	(b) (4)	

US3372184

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Danielle Theodore (b) (4) (b) (4) (b) (4)	17 Nov 2020 18:08:29

US3372184

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:01:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 18:08:29

US3372184

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:01:38

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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 'USA-US056-2020-mRNA-1273-P301000002'	System	07 Sep 2020 16:55:11
User entered 'New'	(b) (4), (b) (6)	07 Sep 2020 16:55:11

US3372184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:38

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	

US3372184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:38

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[AE start 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: 26 Nov 2020 11:01:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3372184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:38

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: 26 Nov 2020 11:01:38

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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).	(b) (4), (b) (6)	03 Nov 2020 18:07:11
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).	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).	(b) (4), (b) (6)	29 Oct 2020 19:41:40
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).	(b) (4), (b) (6)	22 Sep 2020 16:24:42
DataPoint Verified.	(b) (4), (b) (6)	18 Sep 2020 13:31:32
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)	10 Sep 2020 08:19:55
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)	10 Sep 2020 08:12:00
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).	Elena Acosta (b) (4) (b) (4)	03 Sep 2020 17:06:49
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	03 Sep 2020 17:04:23

US3372184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '1'	Elena Acosta (b) (4) (b) (4)	03 Sep 2020 17:04:23

US3372184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:38

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	03 Sep 2020 17:04:23

US3372184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:38

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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
User entered '10 Sep 2020' reason for change: Data Entry Error	Mary Sergalis (b) (4)	19 Oct 2020 18:43:46

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:38

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
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
	(b) (4)	

US3372184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:38

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'PV Query: Apologies for the confusion as action taken was correct as not applicable. Please change back.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 18:07:19
	(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). DataPoint Un-verified.	Mary Sergalis (b) (4)	02 Nov 2020 21:33:36
	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). DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 19:41:04
	(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). 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). DataPoint Un-verified.	(b) (4), (b) (6)	20 Oct 2020 15:09:34
	Mary Sergalis (b) (4)	19 Oct 2020 18:45:07
	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). User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	11 Sep 2020 13:45:21
	Elena Acosta (b) (4)	03 Sep 2020 17:04:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:38

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	03 Sep 2020 17:04:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
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) (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 '1'	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: 26 Nov 2020 11:01:38

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: Data Entry Error	Mary Sergalis (b) (4)	19 Oct 2020 18:45:32
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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:38

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(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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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:38

[Narrative](#)

Audit	User	Time (GMT)
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)	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
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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:38

[Narrative](#)

Audit	User	Time (GMT)
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
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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:38

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (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

US3372184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:38

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 17:04:23

US3372184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 Sep 2020 17:04:23

US3372184

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:01:38

[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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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:38

[Adverse event](#)

Audit	User	Time (GMT)
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

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Mary Sergalis (b) (4)	16 Nov 2020 19:50:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mary Sergalis (b) (4)	16 Nov 2020 19:50:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mary Sergalis (b) (4) [REDACTED] [REDACTED]	16 Nov 2020 19:50:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '28 Aug 2020'	Mary Sergalis (b) (4)	16 Nov 2020 19:50:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:38

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 19:50:55

US3372184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:38

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mary Sergalis (b) (4)	16 Nov 2020 19:50:55

US3372184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '28 Aug 2020'	Mary Sergalis (b) (4)	16 Nov 2020 19:50:55

US3372184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:38

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Mary Sergalis (b) (4)	16 Nov 2020 19:50:55

US3372184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Nov 2020 19:50:55

US3372184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:38

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Mary Sergalis (b) (4)	16 Nov 2020 19:50:55

US3372184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Mary Sergalis (b) (4)	16 Nov 2020 19:50:55

US3372184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:38

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Mary Sergalis (b) (4)	16 Nov 2020 19:50:55

US3372184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:38

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Mary Sergalis (b) (4)	16 Nov 2020 19:50:55

US3372184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Mary Sergalis (b) (4)	16 Nov 2020 19:50:55

US3372184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Mary Sergalis (b) (4)	16 Nov 2020 19:50:55

US3372184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:38

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Mary Sergalis (b) (4)	16 Nov 2020 19:50:55

US3372184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Mary Sergalis (b) (4)	16 Nov 2020 19:50:55

US3372184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Mary Sergalis (b) (4)	16 Nov 2020 19:50:55

US3372184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Mary Sergalis (b) (4)	16 Nov 2020 19:50:55

US3372184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Mary Sergalis (b) (4)	16 Nov 2020 19:50:55

US3372184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:38

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Mary Sergalis (b) (4)	16 Nov 2020 19:50:55

US3372184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
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) (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

US3372184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Mary Sergalis (b) (4)	16 Nov 2020 19:50:55

US3372184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:38

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Mary Sergalis (b) (4)	16 Nov 2020 19:50:55

US3372184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:38

None

Audit	User	Time (GMT)
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	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

US3372184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	Mary Sergalis (b) (4)	16 Nov 2020 19:51:13
User entered '0'	Mary Sergalis (b) (4)	16 Nov 2020 19:50:55

US3372184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Mary Sergalis (b) (4)	16 Nov 2020 19:50:55

US3372184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:38

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 19:51:13
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: Data Entry Error	Mary Sergalis (b) (4) [REDACTED]	16 Nov 2020 19:51:13
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) [REDACTED] [REDACTED]	16 Nov 2020 19:50:55

US3372184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:38

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Mary Sergalis (b) (4)	16 Nov 2020 19:50:55

US3372184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:38

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Mary Sergalis (b) (4)	16 Nov 2020 19:50:55

US3372184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:38

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Nov 2020 19:50:55

US3372184

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:01:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Nov 2020 19:50:55

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:01:38

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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) (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.	Coder Import (b) (4) (b) (4)	14 Oct 2020 18:56:30
Data point term sent to Coder	System	14 Oct 2020 18:55:43
User entered 'propranolol'	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: 26 Nov 2020 11:01:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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) (b) (4)	15 Oct 2020 04:19:22
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 04:19:22
Data point term sent to Coder	System	14 Oct 2020 18:57:45
User entered 'tamsulosin'	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: 26 Nov 2020 11:01:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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) (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 'tamsulosin'	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: 26 Nov 2020 11:01:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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) (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 18:58:49
User entered 'atorvastatin'	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: 26 Nov 2020 11:01:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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) (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) (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) (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) (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) (b) (4)	14 Oct 2020 18:59:46

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:01:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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
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
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

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:01:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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) (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) (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) (b) (4)	14 Oct 2020 19:00:53

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:01:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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) (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) (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) (b) (4)	14 Oct 2020 19:01:40

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:01:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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) (b) (4)	14 Oct 2020 19:02:21

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:01:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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) (b) (4)	14 Oct 2020 19:02:21

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:01:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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) (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) (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) (b) (4)	14 Oct 2020 19:04:34

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 11:01:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 20:12:34
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered '1'	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: 26 Nov 2020 11:01:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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) (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) (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) (b) (4)	14 Oct 2020 19:06:23

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 11:01:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[Name of Medication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 20:17:53
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
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)	11 Nov 2020 19:26:54
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 08:46:53
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.	Coder Import (b) (4) (b) (4)	15 Oct 2020 05:27:30
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	14 Oct 2020 19:10:23
User entered 'corticosteroid injection'	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: 26 Nov 2020 11:01:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Dose per administration](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Prophylaxis](#)

Audit	User	Time (GMT)
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 19:11:02

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 11:01:38

[Indication](#)

Audit	User	Time (GMT)
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) (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: 26 Nov 2020 11:01:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered '500'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:11:02

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 11:01:38

[Dose unit](#)

Audit	User	Time (GMT)
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 19:11:02

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 11:01:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:11:02

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 11:01:38

[Frequency](#)

Audit	User	Time (GMT)
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 19:11:02

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 11:01:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:11:02

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 11:01:38

[Route of administration](#)

Audit	User	Time (GMT)
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 19:11:02

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 11:01:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered empty.	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:11:02

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:02:02
User entered '0'	Peter Jacob (b) (4) (b) (4)	14 Oct 2020 19:11:02

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 11:01:38

[Ongoing?](#)

Audit	User	Time (GMT)
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 19:11:02

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 11:01:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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
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

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 11:01:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:01:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Name of Medication](#)

Audit	User	Time (GMT)
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) (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) (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) (b) (4)	14 Oct 2020 19:12:16

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 11:01:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
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) (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: 26 Nov 2020 11:01:38

[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: 26 Nov 2020 11:01:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Name of Medication](#)

Audit	User	Time (GMT)
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
	(b) (4)	

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 11:01:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 11:01:38

[Indication](#)

Audit	User	Time (GMT)
User entered 'Influenza Prevention'	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: 26 Nov 2020 11:01:38

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '0.5'	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: 26 Nov 2020 11:01:38

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mL (mL)'	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: 26 Nov 2020 11:01:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:38

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	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: 26 Nov 2020 11:01:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:38

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intramuscular (INTRAMUSCULAR)'	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: 26 Nov 2020 11:01:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
User entered '14 Oct 2020'	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: 26 Nov 2020 11:01:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	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: 26 Nov 2020 11:01:38

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 11:01:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '14 Oct 2020'	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: 26 Nov 2020 11:01:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 11:01:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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) (b) (4)	18 Nov 2020 17:13:48

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 11:01:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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) (b) (4) (b) (4)	18 Nov 2020 17:35:44

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 11:01:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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) (b) (4) (b) (4)	18 Nov 2020 17:36:56

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 11:01:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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) (b) (4) (b) (4)	18 Nov 2020 17:38:02

US3372184

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 26 Nov 2020 11:01:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:24:40
User entered '1'	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: 26 Nov 2020 11:01:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	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: 26 Nov 2020 11:01:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 17:40:50

US3372184

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:01:38

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Mary Sergalis (b) (4)	19 Oct 2020 18:51:11
User entered 'No (N)'	Peter Jacob (b) (4)	14 Oct 2020 18:53:38
	(b) (4)	

US3372184

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:01:38

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'Appendectomy'	Mary Sergalis (b) (4)	19 Oct 2020 18:51:39

US3372184

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:01:38

[Indication](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[If indication is Other, specify](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:38

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:38

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:38

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:38

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:38

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:38

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:38

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:38

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 15:17:39
DataPoint Verified.	(b) (4), (b) (6)	16 Sep 2020 14:34:14
User entered '1'	(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: 26 Nov 2020 11:01:38

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:38

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:38

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:38

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:38

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(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 '1'	(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: 26 Nov 2020 11:01:38

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:38

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:38

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:38

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:38

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(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 '1'	(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: 26 Nov 2020 11:01:38

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:38

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:38

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:38

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:38

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 11:01:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 14:08:10
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:23:47
User entered '1'	(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: 26 Nov 2020 11:01:38

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:38

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:38

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 11:01:38

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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

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[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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

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[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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

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Form: Safety Report Form (5)

Generated On: 26 Nov 2020 11:01:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 11:01:38

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	11 Nov 2020 14:08:22