

US3432016 (Prod: Brigham and Womens Hospital)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:24:53

All time stamps listed in this document are displayed in GMT

US3432016

Form: Participant Creation

Generated On: 26 Nov 2020 09:24:53

[Participant ID](#)

US3432016

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

US3432016

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:24:53

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	05 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

US3432016

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:24:53

Date of Birth (MMM yyyy)	(b) (6) 1944
Age	76
Age Units	YEARS
Age (Derived)	76
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

US3432016

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:24:53

Date of Informed Consent (<i>dd MMM yyyy</i>)	05 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

US3432016

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:24:53

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3432016

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:24:53

Were any significant conditions reported?

Yes ☒

No ☐

US3432016

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:24:53

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3432016

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:24:53

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	
Stop Year (derived)	

US3432016

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:24:53

Condition	ALLERGIC RHINITIS
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

US3432016

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:24:53

Condition	ATRIAL FIBRILLATION
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)	

US3432016

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:24:53

Condition	BRADYCARDIA
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3432016

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:24:53

Condition	ASTHMA
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)	

US3432016

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:24:53

Condition	HEART MURMUR
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

US3432016

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:24:53

Condition	COPD
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3432016

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:24:53

Condition	PNEUMONIA
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)	UN UNK 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

US3432016

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:24:53

Condition	OSTEOARTHRITIS
Start date (dd MMM yyyy)	UN UNK 2011
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 2011
Start Year (derived)	2011
Stop Month and Year (derived)	
Stop Year (derived)	

US3432016

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:24:53

Condition	BLADDER SLING
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2010
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	JAN 2010
Stop Year (derived)	2010

US3432016

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:24:53

Condition	GLUTEN SENSITIVITY
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)	

US3432016

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:24:53

Condition	HYSTERECTOMY
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

US3432016

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:24:53

Condition	UVULA REMOVAL
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)	UN UNK 1995
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	JAN 1995
Stop Year (derived)	1995

US3432016

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:24:53

Condition	PARTIAL THYROIDECTOMY
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)	UN UNK 1995
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	JAN 1995
Stop Year (derived)	1995

US3432016

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:24:53

Condition	KNEE REPLACEMENT
Start date (dd MMM yyyy)	UN UNK 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2011
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2011
Start Year (derived)	2011
Stop Month and Year (derived)	JAN 2011
Stop Year (derived)	2011

US3432016

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:24:53

Condition	HIP REPLACEMENT
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)	UN UNK 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

US3432016

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:24:53

Condition	TONSILLECTOMY
Start date (dd MMM yyyy)	UN UNK 1960
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1960
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1960
Start Year (derived)	1960
Stop Month and Year (derived)	JAN 1960
Stop Year (derived)	1960

US3432016

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:24:53

Condition	WATCHMAN PROCEDURE FOR ATRIAL FIBRILLATION
Start date (dd MMM yyyy)	UN NOV 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN NOV 2019
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2019
Start Year (derived)	2019
Stop Month and Year (derived)	NOV 2019
Stop Year (derived)	2019

US3432016

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:24:53

Condition	CARPAL TUNNEL SURGERY
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)	UN UNK 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

US3432016

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:24:53

Condition	TRIGGER FINGER SURGERY
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

US3432016

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:24:53

Condition	CATARACT SURGERY
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

US3432016

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:24:53

Condition	CHOLECYSTECTOMY
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

US3432016

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 09:24:53

Condition	GERD
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3432016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:53

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	05 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	08:31 (24 HR)
Vital Signs Date and Time (derived)	05 AUG 2020 08:31
Height (<i>xxx.x</i>)	161 cm
Weight (<i>xxx.x</i>)	93.2 kg
BMI (<i>xxx.x</i>)	35.95540 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)	

US3432016

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:24:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

05 AUG 2020

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

US3432016

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:24:53

Date of assessment (<i>dd MMM yyyy</i>)	05 AUG 2020
Is the participant of childbearing potential?	Yes ☐
	No ☒
If No, what is the reason?	Surgically sterile ☐
	Post-menopausal ☒
	Partner medically sterile ☐
	Not reached age of Menarche ☐
	Other ☐
If Partner medically sterile or Other, specify _____	
If Surgically sterile, date of surgery (<i>dd MMM yyyy</i>) _____	
Date of surgery unknown	False
If Post-menopausal, date of last menstruation (<i>dd MMM yyyy</i>)	UN UNK 2005
Date of last menstruation unknown	False

US3432016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:53

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 RETIRED

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

US3432016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:53

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	

US3432016

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:24:53

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	05 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

US3432016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:24:53

What was the date of randomization? (dd MMM yyyy) 05 AUG 2020

What was the participant's randomization number? 184650

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 ☒

US3432016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:24:53

Height	ND - Not Done
Weight	ND - Not Done

US3432016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:53

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)	05 AUG 2020
Time of assessment (00:00-23:59)	08:31 (24 HR)
Vital Signs Date and Time (derived)	05 AUG 2020 08:31
Temperature (xxx.x)	36.9 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3432016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:53

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)	05 AUG 2020
Time of assessment (00:00-23:59)	10:29 (24 HR)
Vital Signs Date and Time (derived)	05 AUG 2020 10:29
Temperature (xxx.x)	37 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3432016

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:24:53

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.

US3432016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:24:53

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) 05 AUG 2020

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

Treatment Date and Time (derived) 05 AUG 2020 09:59

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

US3432016

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:24:53

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	05 AUG 2020
Collection time (<i>00:00-23:59</i>)	09:09 (24 HR)
Collection date and time (derived)	05 AUG 2020 09:09

US3432016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:24:53

Collection date (<i>dd MMM yyyy</i>)			05 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	09:15	05 AUG 2020 09:15
Nasopharyngeal Swab 2	No		

US3432016

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:24:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 AUG 2020 10:31

PC Open Date & Time

05 AUG 2020 10:19

PC Close Date & Time

05 AUG 2020 12:49

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

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

98.5 °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

05 AUG 2020 16:58

PC Open Date & Time

05 AUG 2020 13:44

PC Close Date & Time

06 AUG 2020 11:59

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:24:53

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

97.7 °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

06 AUG 2020 16:58

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:24:53

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

07 AUG 2020 15:11

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:24:53

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

97.8 °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

08 AUG 2020 16:13

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:24:53

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

99.1 °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

09 AUG 2020 17:00

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:24:53

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

98.5 °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

10 AUG 2020 16:12

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:24:53

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

98.4 °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

11 AUG 2020 17:53

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

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

05 AUG 2020 10:32

PC Open Date & Time

05 AUG 2020 10:19

PC Close Date & Time

05 AUG 2020 12:49

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

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

05 AUG 2020 16:59

PC Open Date & Time

05 AUG 2020 13:44

PC Close Date & Time

06 AUG 2020 11:59

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:24:53

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

06 AUG 2020 17:00

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:24:53

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

07 AUG 2020 15:12

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:24:53

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

08 AUG 2020 16:14

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:24:53

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

09 AUG 2020 17:01

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:24:53

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

10 AUG 2020 16:12

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:24:53

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

11 AUG 2020 17:53

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

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

No ☒

Yes ☐

PC Time stamp	05 AUG 2020 10:33
PC Open Date & Time	05 AUG 2020 10:19
PC Close Date & Time	05 AUG 2020 12:49

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

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

No ☒

Yes ☐

PC Time stamp	05 AUG 2020 17:00
PC Open Date & Time	05 AUG 2020 13:44
PC Close Date & Time	06 AUG 2020 11:59

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:24:53

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 ☒

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:24:53

Yes ☐	
PC Time stamp	06 AUG 2020 17:01
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:24:53

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 ☒

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:24:53

Yes ☐	
PC Time stamp	07 AUG 2020 15:13
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:24:53

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 ☒

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:24:53

Yes ☐	
PC Time stamp	08 AUG 2020 16:15
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:24:53

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 ☒

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:24:53

Yes ☐	
PC Time stamp	09 AUG 2020 17:01
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:24:53

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 ☒

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:24:53

Yes ☐	
PC Time stamp	10 AUG 2020 16:13
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:24:53

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 ☒

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:24:53

Yes ☐	
PC Time stamp	11 AUG 2020 17:54
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3432016

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432016

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432016

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

19 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432016

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432016

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432016

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:24:53

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	02 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3432016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:53

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	02 SEP 2020
Time of assessment (00:00-23:59)	08:46 (24 HR)
Vital Signs Date and Time (derived)	02 SEP 2020 08:46
Temperature (xxx.x)	36.7 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3432016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:53

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	2 SEP 2020
Time of assessment (00:00-23:59)	10:43 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 10:43
Temperature (xxx.x)	98.4 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3432016

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:24:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 SEP 2020

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

US3432016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:24:53

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)	02 SEP 2020
What was the treatment time? (00:00-23:59)	10:13 (24 HR)
Treatment Date and Time (derived)	02 SEP 2020 10:13
Which arm was used to give treatment?	Left Arm ☒
	Right Arm ☐
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

US3432016

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:24:53

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	02 SEP 2020
Collection time (<i>00:00-23:59</i>)	09:35 (24 HR)
Collection date and time (derived)	02 SEP 2020 09:35

US3432016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:24:53

Collection date (dd MMM yyyy)			02 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:22	02 SEP 2020 09:22
Nasopharyngeal Swab 2	No		

US3432016

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 10:50

PC Open Date & Time

02 SEP 2020 10:33

PC Close Date & Time

02 SEP 2020 13:03

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

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 98.2 °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	02 SEP 2020 15:39
PC Open Date & Time	02 SEP 2020 13:58
PC Close Date & Time	03 SEP 2020 11:59

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:24:53

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

100.7 °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

03 SEP 2020 15:52

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

04 SEP 2020 16:19

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

05 SEP 2020 15:59

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:24:53

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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 17:31

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:24:53

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	98.4 °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):

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	True
PC Time Stamp	07 SEP 2020 15:43
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 15:53

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

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

02 SEP 2020 10:50

PC Open Date & Time

02 SEP 2020 10:33

PC Close Date & Time

02 SEP 2020 13:03

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

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

02 SEP 2020 15:40

PC Open Date & Time

02 SEP 2020 13:58

PC Close Date & Time

03 SEP 2020 11:59

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:24:53

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

03 SEP 2020 15:52

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:24:53

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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

7

Measure the largest size across any injection site redness with the
ruler provided.

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

Yes ☒

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE
(in mm)**

7

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 16:21

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:24:53

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

05 SEP 2020 16:01

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:24:53

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

06 SEP 2020 17:31

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:24:53

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

07 SEP 2020 15:44

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:24:53

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

08 SEP 2020 15:54

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 10:51
PC Open Date & Time	02 SEP 2020 10:33
PC Close Date & Time	02 SEP 2020 13:03

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 15:40
PC Open Date & Time	02 SEP 2020 13:58
PC Close Date & Time	03 SEP 2020 11:59

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:24:53

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 ☒

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:24:53

Yes ☐	
PC Time stamp	03 SEP 2020 15:54
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:24:53

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 ☒

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:24:53

Yes ☐	
PC Time stamp	04 SEP 2020 16:21
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:24:53

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 ☒

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:24:53

Yes ☐	
PC Time stamp	05 SEP 2020 16:02
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:24:53

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 ☒

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:24:53

Yes ☐	
PC Time stamp	06 SEP 2020 17:32
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:24:53

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 ☒

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:24:53

Yes ☐	
PC Time stamp	07 SEP 2020 15:45
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:24:53

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 ☒

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:24:53

Yes ☐	
PC Time stamp	08 SEP 2020 15:55
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3432016

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432016

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432016

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432016

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432016

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432016

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432016

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:24:53

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	30 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3432016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:53

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	30 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	10:10 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 10:10
Temperature (<i>xxx.x</i>)	98.0 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	90 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	58 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3432016

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:24:53

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.

US3432016

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:24:53

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	30 SEP 2020
Collection time (<i>00:00-23:59</i>)	10:28 (24 HR)
Collection date and time (derived)	30 SEP 2020 10:28

US3432016

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

05 OCT 2020 15:53:28

Patient Cloud Open Date & Time

05 OCT 2020 00:01

Patient Cloud Close Date & Time

09 OCT 2020 23:59

US3432016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

12 OCT 2020 13:28:53

Patient Cloud Open Date & Time

12 OCT 2020 00:01

Patient Cloud Close Date & Time

16 OCT 2020 23:59

US3432016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

19 OCT 2020 15:52:19

Patient Cloud Open Date & Time

19 OCT 2020 00:01

Patient Cloud Close Date & Time

23 OCT 2020 23:59

US3432016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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	02 NOV 2020 12:20:54
Patient Cloud Open Date & Time	02 NOV 2020 00:01
Patient Cloud Close Date & Time	06 NOV 2020 23:59

US3432016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 NOV 2020 12:27:12

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3432016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

DAY 106

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 NOV 2020 12:01:43

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2020 23:59

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

[Patient Cloud Close Date & Time](#)

13 OCT 2020 23:59

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 05:52:22
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

[Patient Cloud Close Date & Time](#)

26 JAN 2021 23:59

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

[Patient Cloud Close Date & Time](#)

16 FEB 2021 23:59

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

[Patient Cloud Close Date & Time](#)

23 FEB 2021 23:59

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

[Patient Cloud Close Date & Time](#)

13 APR 2021 23:59

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

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](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

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](#)

12 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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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25 MAR 2022 00:01

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29 MAR 2022 23:59

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

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05 APR 2022 23:59

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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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19 APR 2022 23:59

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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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26 APR 2022 23:59

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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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10 MAY 2022 23:59

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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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17 MAY 2022 23:59

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

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

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US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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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31 MAY 2022 23:59

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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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03 JUN 2022 00:01

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07 JUN 2022 23:59

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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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21 JUN 2022 23:59

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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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28 JUN 2022 23:59

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

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05 JUL 2022 23:59

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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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08 JUL 2022 00:01

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12 JUL 2022 23:59

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

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19 JUL 2022 23:59

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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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22 JUL 2022 00:01

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26 JUL 2022 23:59

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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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29 JUL 2022 00:01

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02 AUG 2022 23:59

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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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05 AUG 2022 00:01

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09 AUG 2022 23:59

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

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16 AUG 2022 23:59

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

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23 AUG 2022 23:59

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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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26 AUG 2022 00:01

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30 AUG 2022 23:59

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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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06 SEP 2022 23:59

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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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13 SEP 2022 23:59

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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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16 SEP 2022 00:01

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20 SEP 2022 23:59

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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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23 SEP 2022 00:01

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27 SEP 2022 23:59

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

27 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432016

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432016

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:53

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3432016

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:24:53

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3432016

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:24:53

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3432016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:53

AEID	
Adverse event	FEVER
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)	3 SEP 2020
Start time (00:00-23:59)	00:00 (24 HR)
AE start date and time (derived)	3 SEP 2020 00:00
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	4 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	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False
v6.020 DTW (1102)	359 of 2438

US3432016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:53

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)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3432016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:24:53

AEID	USA-US078-2020-MRNA-1273-P30 1000008
Adverse event	GERD
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)	22 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	24 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☒ Grade 4 ☐
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	24 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	24 OCT 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	
v6.020 DTW (1102)	361 of 2438

US3432016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:24:53

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	

US3432016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:24:53

PT CONSULTED TO URGENT
CARE ON 23 OCT2020 FOR
EPIGASTRIC PAIN, NAUSEA,
VOMITING AND TRANSFERRED
TO THE ED. RECEIVED ZOFRAN
AND SIGNIFICANTLY
IMPROVED. IN THE CONTEXT
OF THE GI ILLNESS, WAS ALSO
FOUND TO HAVE RAPID A. FIB
(A-FIB ALREADY IN MED HX)
FOR WHICH THEY RECEIVED
METOPROLOL IV X1. WAS
ADMITTED EARLY 24OCT2020
FOR MONITORING.

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

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:24:53

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

Yes ☒

No ☐

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

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:24:53

Name of Medication	CRANBERRY SUPPLEMENT
Prophylaxis	Yes ☐ No ☒
Indication	GENERAL HEALTH
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 ☐

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:24:53

	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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:24:53

Name of Medication	N-ACETYL CYSTEINE SUPPLEMENT (ACETYLCYSTEINE)
Prophylaxis	Yes ☐ No ☒
Indication	MUCOUS PRODUCTION
Dose per administration	600
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 ☐

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:24:53

	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 2015
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	☐

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:24:53

Name of Medication	FLUTICASONE INTRANASAL
Prophylaxis	Yes ☐ No ☒
Indication	ALLERGIC RHINITIS
Dose per administration	2
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	SPRAY
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 ☐

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:24:53

	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	☐

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:24:53

Name of Medication	AMOXICILLIN
Prophylaxis	Yes ☒ No ☐
Indication	DENTAL PROPHYLAXIS
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 ☐

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:24:53

	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)		22 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		22 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 ☐

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:24:53

Name of Medication	BIOTIN
Prophylaxis	Yes ☐ No ☒
Indication	GENERAL HEALTH
Dose per administration	3000
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 ☐

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:24:53

	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	☒

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:24:53

Name of Medication	LUTEIN
Prophylaxis	Yes ☐ No ☒
Indication	GENERAL HEALTH
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 ☐

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:24:53

	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	☒

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:24:53

Name of Medication	SUBLINGUAL IMMUNOTHERAPY SOLUTION (SLIT SOLUTION)
Prophylaxis	Yes ☐ No ☒
Indication	ALLERGIC RHINITIS
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	PUMP
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 ☐

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:24:53

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☒
If route of administration is Other, specify	SUBLINGUAL	
Start date (dd MMM yyyy)	01 MAY 2020	
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)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:24:53

Name of Medication	ASPIRIN
Prophylaxis	Yes ☐ No ☒
Indication	ATRIAL FIBRILLATION
Dose per administration	81
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:24:53

	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	☒

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:24:53

Name of Medication	LISINOPRIL
Prophylaxis	Yes ☐ No ☒
Indication	HYPERTENSION
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 ☐ Intramuscular ☐

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:24:53

	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)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:24:53

Name of Medication	HYDROCHLOROTHIAZIDE
Prophylaxis	Yes ☐ No ☒
Indication	HYPERTENSION
Dose per administration	50
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:24:53

	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)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:24:53

Name of Medication	MONTELUKAST
Prophylaxis	Yes ☐ No ☒
Indication	ALLERGIC RHINITIS
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 ☐

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:24:53

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)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☒

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:24:53

Name of Medication	SIMVASTATIN
Prophylaxis	Yes ☐ No ☒
Indication	HYPERLIPIDEMIA
Dose per administration	20
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:24:53

	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)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:24:53

Name of Medication	RESTASIS EYE DROPS
Prophylaxis	Yes ☐ No ☒
Indication	DRY EYES
Dose per administration	2
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	DROPS
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 ☐

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:24:53

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☒
If route of administration is Other, specify	OCULAR	
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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:24:53

Name of Medication	ADVAIR DISKUS
Prophylaxis	Yes ☐ No ☒
Indication	ASTHMA
Dose per administration	500/50
Dose unit	mg ☐ ug ☒ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☐ twice daily ☒ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:24:53

	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)	31 AUG 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	☒

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:24:53

Name of Medication	VENTOLIN
Prophylaxis	Yes ☐ No ☒
Indication	ASTHMA
Dose per administration	2
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☒ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:24:53

	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	☐

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:24:53

Name of Medication	AMOXICILLIN
Prophylaxis	Yes ☒ No ☐
Indication	DENTAL PROPHYLAXIS
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 ☐

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:24:53

	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)		
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	☐

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:24:53

Name of Medication	IBUPROFEN
Prophylaxis	Yes ☐ No ☒
Indication	OSTEOARTHRITIS
Dose per administration	600
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 ☐

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:24:53

	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)		
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	☐

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:24:53

Name of Medication	MULTIVITAMIN
Prophylaxis	Yes ☐ No ☒
Indication	GENERAL HEALTH
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 ☐

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:24:53

	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)		
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	☒

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:24:53

Name of Medication	VITAMIN C
Prophylaxis	Yes ☐ No ☒
Indication	GENERAL HEALTH
Dose per administration	10,000
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 ☐

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:24:53

	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)		
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	☒

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:24:53

Name of Medication	CURCUMAX
Prophylaxis	Yes ☐ No ☒
Indication	GENERAL HEALTH
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 ☐

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:24:53

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)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☒

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:24:53

Name of Medication MYOCALM PLUS (CALCIUM, MAGNESIUM, PASSIONFLOWER FLOWER 5.5:1 EXTRACT, VALERIAN ROOT EXTRACT, HOPS CONE 7.5:1 EXTRACT, LEMON BALM LEAF 4:1 EXTRACT)

Prophylaxis Yes ☐ No ☒

Indication GENERAL HEALTH

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 ☒

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:24:53

	Topical	☐
	Subcutaneous	☐
	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 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)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:24:53

Name of Medication	PROBIOTIC ULTRAFLORESPECTRUM
Prophylaxis	Yes ☐ No ☒
Indication	GENERAL HEALTH
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 ☐

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:24:53

	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 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)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:24:53

Name of Medication	ADVAIR DISKUS
Prophylaxis	Yes ☐ No ☒
Indication	ASTHMA
Dose per administration	500/50
Dose unit	mg ☐ ug ☒ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☐ twice daily ☒ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:24:53

	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)		01 SEP 2020
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	☒

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:24:53

Name of Medication	IBUPROFEN
Prophylaxis	Yes ☐ No ☒
Indication	DENTAL PROCEDURE PAIN MANAGEMENT
Dose per administration	600
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 ☐

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:24:53

	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)		22 SEP 2020
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	☐

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:24:53

Name of Medication	INFLUENZA VACCINE
Prophylaxis	Yes ☒ No ☐
Indication	PROPHYLAXIS
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	INJECTION
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 ☒

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:24:53

	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)		17 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		17 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	☐

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:24:53

Name of Medication	AMOXICILLIN
Prophylaxis	Yes ☒ No ☐
Indication	PROPHYLAXIS DENTAL PROCEDURES
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 ☐

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:24:53

	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)		09 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		09 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	☐

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:24:53

Name of Medication	METROPROLOL
Prophylaxis	Yes ☐ No ☒
Indication	A-FIB
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 ☐ Intramuscular ☐

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:24:53

	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)	23 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		23 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	☐

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:24:53

	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)		23 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		23 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	☐

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 09:24:53

Name of Medication	ACETAMINOPHEN
Prophylaxis	Yes ☐ No ☒
Indication	MILD PAIN
Dose per administration	650
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☒
If frequency is Other, specify	
Route of administration	EVERY 6 HOURS Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 09:24:53

	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)		24 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		24 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	☐

US3432016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:24:53

[Were any concomitant procedures performed?](#)

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3432016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 09:24:53

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
24 AUG 2020	CT SCAN	Diagnostic	
9 SEP 2020	DENTAL IMPLANT	Other	DENTAL CARE
22 SEP 2020	DENTAL IMPLANT	Other	DENTAL CARE
27 AUG 2020	BREATHING TEST	Diagnostic	
15 SEP 2020	MAMMOGRAM	Diagnostic	

US3432016

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:24:53

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

US3432016

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:24:53

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 ☐

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

SAEID	USA-US078-2020-MRNA-1273-P301000008
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	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:24:53

SAEID	USA-US078-2020-MRNA-1273-P301000008
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	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	26/OCT/2020 16:49
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

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:24:53

SAEID	USA-US078-2020-MRNA-1273-P301000008
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	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	06/NOV/2020 19:33
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

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:24:53

SAEID	USA-US078-2020-MRNA-1273-P301000008
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	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	11/NOV/2020 14:26
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

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:24:53

SAEID	USA-US078-2020-MRNA-1273-P301000008
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	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	23/NOV/2020 21:53
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

US3432016 (Prod: Brigham and Womens Hospital)

US3432016

Form: Participant Creation

Generated On: 26 Nov 2020 09:24:53

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 17:40:36
User entered 'US3432016'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 12:34:15

US3432016

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:24:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 17:43:24
User entered 'Yes (Y)'	Natalie Izaguirre (b) (4)	05 Aug 2020 13:25:06

US3432016

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 17:43:24
User entered '05 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 12:34:16

US3432016

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 17:43:24
User entered 'Clinic (Clinic)'	Natalie Izaguirre (b) (4)	05 Aug 2020 13:25:06

US3432016

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:24:53

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	05 Aug 2020 13:25:06

US3432016

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:24:53

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 17:44:02
User entered (b) (6) 1944'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 12:34:17

US3432016

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:24:53

[Age](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 17:44:02
User entered '76'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:29:24

US3432016

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:24:53

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	05 Aug 2020 18:29:24

US3432016

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:24:53

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '76'	System	05 Aug 2020 13:25:40

US3432016

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:24:53

[Sex](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 17:44:02
User entered 'Female (F)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:29:24

US3432016

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:24:53

[Ethnicity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 17:44:02
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:29:24

US3432016

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:24:53

[White](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 17:44:02
User entered '1'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:29:24

US3432016

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:24:53

[Black](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 17:44:02
User entered '0'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:29:24

US3432016

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:24:53

[Asian](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 17:44:02
User entered '0'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:29:24

US3432016

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:24:53

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 17:44:02
User entered '0'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:29:24

US3432016

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:24:53

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 17:44:02
User entered '0'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:29:24

US3432016

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:24:53

[Other](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 17:44:02
User entered '0'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:29:24

US3432016

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:24:53

[If race is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 17:44:02
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:29:24

US3432016

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:24:53

[Unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 17:44:02
User entered '0'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:29:24

US3432016

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:24:53

[Not reported](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 17:44:02
User entered '0'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:29:24

US3432016

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:24:53

Date of Informed Consent (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 17:45:34
User entered '05 Aug 2020'	Natalie Izaguirre (b) (4)	05 Aug 2020 13:25:40

US3432016

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	05 Aug 2020 13:25:40

US3432016

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered '2020'	System	05 Aug 2020 13:25:40

US3432016

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:24:53

[Protocol Version](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 17:45:34
User entered 'Amendment 1 (1)'	Natalie Izaguirre (b) (4)	05 Aug 2020 13:25:40

US3432016

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 17:45:34
User entered 'Yes (Y)'	Natalie Izaguirre (b) (4)	05 Aug 2020 13:25:40

US3432016

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:24:53

If No, indicate reason for screen fail

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 17:45:34
User entered empty.	Natalie Izaguirre (b) (4)	05 Aug 2020 13:25:40

US3432016

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:24:53

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 17:45:34
User entered empty.	Natalie Izaguirre (b) (4)	05 Aug 2020 13:25:40

US3432016

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:24:53

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 17:45:34
User entered 'No (N)'	Natalie Izaguirre (b) (4)	05 Aug 2020 13:25:40

US3432016

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:24:53

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 17:45:34
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 12:34:16

US3432016

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:24:53

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 13:25:46

US3432016

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 17:56:13
User entered 'Yes (Y)'	Natalie Izaguirre (b) (4)	05 Aug 2020 13:25:46

US3432016

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:24:53

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 17:49:32
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:56:16

US3432016

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:24:53

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:02:09
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Aug 2020 18:58:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Aug 2020 18:58:04
Data point term sent to Coder	System	05 Aug 2020 18:57:26
User entered 'Hypertension'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:56:43

US3432016

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:02:09
User entered 'UN UNK 2010'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:56:43

US3432016

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:24:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:02:09
User entered '0'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:56:43

US3432016

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:24:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:02:09
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:56:43

US3432016

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:02:09
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:56:43

US3432016

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:24:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:02:09
User entered '0'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:56:43

US3432016

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	05 Aug 2020 18:56:43

US3432016

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered '2010'	System	05 Aug 2020 18:56:43

US3432016

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 18:56:43

US3432016

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 18:56:43

US3432016

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:24:53

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:02:09
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Aug 2020 18:58:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Aug 2020 18:58:04
Data point term sent to Coder	System	05 Aug 2020 18:57:26
User entered 'Hyperlipidemia'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:57:26

US3432016

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:02:09
User entered 'UN UNK 2012'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:57:26

US3432016

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:24:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:02:09
User entered '0'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:57:26

US3432016

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:24:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:02:09
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:57:26

US3432016

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:02:09
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:57:26

US3432016

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:24:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:02:09
User entered '0'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:57:26

US3432016

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered 'Jan 2012'	System	05 Aug 2020 18:57:26

US3432016

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered '2012'	System	05 Aug 2020 18:57:26

US3432016

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 18:57:26

US3432016

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 18:57:26

US3432016

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:24:53

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:02:09
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Rhinitis allergic, LLT: Allergic rhinitis - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 18:59:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	05 Aug 2020 18:59:00
Data point term sent to Coder	System	05 Aug 2020 18:58:27
User entered 'Allergic Rhinitis'	Julia Klopfer (b) (4)	05 Aug 2020 18:57:51
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:02:09
User entered 'UN UNK 2000'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:57:51

US3432016

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:24:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:02:09
User entered '0'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:57:51

US3432016

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:24:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:02:09
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:57:51

US3432016

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:02:09
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:57:51

US3432016

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:24:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:02:09
User entered '0'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:57:51

US3432016

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	05 Aug 2020 18:57:51

US3432016

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered '2000'	System	05 Aug 2020 18:57:51

US3432016

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 18:57:51

US3432016

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 18:57:51

US3432016

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:24:53

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:02:09
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Aug 2020 18:59:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Aug 2020 18:59:00
Data point term sent to Coder	System	05 Aug 2020 18:58:29
User entered 'Atrial Fibrillation'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:58:20

US3432016

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:02:09
User entered 'UN UNK 2019'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:58:20

US3432016

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:24:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:02:09
User entered '0'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:58:20

US3432016

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:24:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:02:09
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:58:20

US3432016

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:02:09
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:58:20

US3432016

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:24:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:02:09
User entered '0'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:58:20

US3432016

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	05 Aug 2020 18:58:20

US3432016

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered '2019'	System	05 Aug 2020 18:58:20

US3432016

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 18:58:20

US3432016

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 18:58:20

US3432016

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:24:53

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:02:09
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Bradycardia, LLT: Bradycardia - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 19:00:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	05 Aug 2020 19:00:03
Data point term sent to Coder	System	05 Aug 2020 18:59:31
User entered 'Bradycardia'	Julia Klopfer (b) (4)	05 Aug 2020 18:58:46
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:02:09
User entered 'UN UNK 2012'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:58:46

US3432016

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:24:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:02:09
User entered '0'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:58:46

US3432016

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:24:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:02:09
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:58:46

US3432016

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:02:09
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:58:46

US3432016

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:24:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:02:09
User entered '0'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:58:46

US3432016

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered 'Jan 2012'	System	05 Aug 2020 18:58:46

US3432016

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered '2012'	System	05 Aug 2020 18:58:46

US3432016

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 18:58:46

US3432016

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 18:58:46

US3432016

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:24:53

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:02:09
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 19:00:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	05 Aug 2020 19:00:58
Data point term sent to Coder	System	05 Aug 2020 18:59:33
User entered 'Asthma'	Julia Klopfer (b) (4)	05 Aug 2020 18:59:05
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:02:09
User entered 'UN UNK 2005'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:59:05

US3432016

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:24:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:02:09
User entered '0'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:59:05

US3432016

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:24:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:02:09
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:59:05

US3432016

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:02:09
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:59:05

US3432016

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:24:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:02:09
User entered '0'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:59:05

US3432016

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	05 Aug 2020 18:59:05

US3432016

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered '2005'	System	05 Aug 2020 18:59:05

US3432016

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 18:59:05

US3432016

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 18:59:05

US3432016

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:24:53

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:02:09
User coded data point as SOC: Investigations, HLGT: Cardiac and vascular investigations (excl enzyme tests), HLT: Cardiac auscultatory investigations, PT: Cardiac murmur, LLT: Heart murmur - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 19:00:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 19:00:58
Data point term sent to Coder	System	05 Aug 2020 18:59:33
User entered 'Heart Murmur'	Julia Klopfer (b) (4)	05 Aug 2020 18:59:23
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:02:09
User entered 'UN UNK 2010'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:59:23

US3432016

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:24:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:02:09
User entered '0'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:59:23

US3432016

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:24:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:02:09
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:59:23

US3432016

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:02:09
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:59:23

US3432016

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:24:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:02:09
User entered '0'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:59:23

US3432016

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	05 Aug 2020 18:59:23

US3432016

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered '2010'	System	05 Aug 2020 18:59:23

US3432016

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 18:59:23

US3432016

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 18:59:23

US3432016

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:24:53

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no Con Med listed for this condition and treatment would be expected. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 18:02:31
Query 'Per DM CLR: Please note that there is no Con Med listed for this condition and treatment would be expected. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'participant did not report medication' (Site from DM).	Monica Feeley (b) (4)	01 Oct 2020 15:50:06
User opened query 'Per DM CLR: Please note that there is no Con Med listed for this condition and treatment would be expected. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 13:33:56
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:02:09
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: COPD - version MedDRA\23.0.	Coder Import (b) (4)	05 Aug 2020 19:00:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Aug 2020 19:00:58
Data point term sent to Coder	System	05 Aug 2020 19:00:36
User entered 'COPD'	Julia Klopfer (b) (4)	05 Aug 2020 18:59:58

US3432016

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:02:09
User entered 'UN UNK 2010'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:59:58

US3432016

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:24:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:02:09
User entered '0'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:59:58

US3432016

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:24:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:02:09
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:59:58

US3432016

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:02:09
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:59:58

US3432016

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:24:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:02:09
User entered '0'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 18:59:58

US3432016

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	05 Aug 2020 18:59:58

US3432016

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered '2010'	System	05 Aug 2020 18:59:58

US3432016

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 18:59:58

US3432016

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 18:59:58

US3432016

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:24:53

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:02:09
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Pneumonia - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 19:00:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 19:00:58
Data point term sent to Coder	System	05 Aug 2020 19:00:37
User entered 'Pneumonia'	Julia Klopfer (b) (4)	05 Aug 2020 19:00:25
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:02:09
User entered 'UN UNK 2017'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:00:25

US3432016

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:24:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:02:09
User entered '0'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:00:25

US3432016

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:24:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:02:09
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:00:25

US3432016

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:02:09
User entered 'UN UNK 2017'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:00:25

US3432016

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:24:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:02:09
User entered '0'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:00:25

US3432016

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	05 Aug 2020 19:00:25

US3432016

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered '2017'	System	05 Aug 2020 19:00:25

US3432016

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	05 Aug 2020 19:00:25

US3432016

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered '2017'	System	05 Aug 2020 19:00:25

US3432016

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:24:53

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update medical history diagnosis as appropriate. If term refers to RHEUMATOID ARTHRITIS, please provide its corresponding Con Med as treatment is expected for this condition. Also ensure update to MHx is reconciled with any corresponding AE if applicable.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 18:03:04
Query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update medical history diagnosis as appropriate. If term refers to RHEUMATOID ARTHRITIS, please provide its corresponding Con Med as treatment is expected for this condition. Also ensure update to MHx is reconciled with any corresponding AE if applicable.' answered with 'osteoarthritis in joints' (Site from DM).	Jessica Cauley (b) (4)	06 Oct 2020 13:46:02
User opened query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update medical history diagnosis as appropriate. If term refers to RHEUMATOID ARTHRITIS, please provide its corresponding Con Med as treatment is expected for this condition. Also ensure update to MHx is reconciled with any corresponding AE if applicable.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 13:34:19
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:52:41
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\23.0.	Coder Import (b) (4)	02 Sep 2020 22:57:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	02 Sep 2020 22:57:48
Data point term sent to Coder	System	02 Sep 2020 22:56:24
Coding entries removed.	Julia Klopfer (b) (4)	02 Sep 2020 22:55:30
User entered 'osteoARTHRITIS' reason for change:	Julia Klopfer (b) (4)	02 Sep 2020 22:55:30
Data Entry Error	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:24:53

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Arthritis - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 23:32:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 23:32:47
Data point term sent to Coder	System	18 Aug 2020 21:13:59
User entered 'arthritis'	Xhoi Mitre (b) (4)	18 Aug 2020 21:13:02
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:52:41
User entered 'UN UNK 2011'	Xhoi Mitre (b) (4) (b) (4)	18 Aug 2020 21:13:02

US3432016

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:24:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:52:41
User entered '0'	Xhoi Mitre (b) (4)	18 Aug 2020 21:13:02
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:24:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:52:41
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	18 Aug 2020 21:13:02
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:52:41
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	18 Aug 2020 21:13:02

US3432016

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:24:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:52:41
User entered '0'	Xhoi Mitre (b) (4)	18 Aug 2020 21:13:02
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered 'Jan 2011'	System	18 Aug 2020 21:13:02

US3432016

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered '2011'	System	18 Aug 2020 21:13:02

US3432016

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 21:13:02

US3432016

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 21:13:02

US3432016

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:24:53

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 18:27:16
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'Will follow up with participant at next scheduled appointment.' (Site from DM).	Alexander Mills (b) (4)	03 Nov 2020 18:42:12
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 04:32:39
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User coded data point as SOC: Surgical and medical procedures, HLGT: Renal and urinary tract therapeutic procedures, HLT: Bladder therapeutic procedures, PT: Urinary bladder suspension, LLT: Bladder sling procedure - version MedDRA\23.0.	Coder Import (b) (4)	30 Sep 2020 15:13:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	30 Sep 2020 15:13:54
Data point term sent to Coder	System	30 Sep 2020 15:12:43
User entered 'Bladder sling'	Julia Klopfer (b) (4)	30 Sep 2020 15:12:01

US3432016

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered 'UN UNK 2010'	Julia Klopfer (b) (4) (b) (4)	30 Sep 2020 15:12:01

US3432016

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:24:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered '0'	Julia Klopfer (b) (4) (b) (4)	30 Sep 2020 15:12:01

US3432016

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:24:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	30 Sep 2020 15:12:01

US3432016

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered 'UN UNK 2010'	Julia Klopfer (b) (4) (b) (4)	30 Sep 2020 15:12:01

US3432016

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:24:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered '0'	Julia Klopfer (b) (4) (b) (4)	30 Sep 2020 15:12:01

US3432016

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	30 Sep 2020 15:12:01

US3432016

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered '2010'	System	30 Sep 2020 15:12:01

US3432016

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	30 Sep 2020 15:12:01

US3432016

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered '2010'	System	30 Sep 2020 15:12:01

US3432016

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:24:53

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Food intolerance syndromes, HLT: Food malabsorption and intolerance syndromes (excl sugar intolerance), PT: Gluten sensitivity, LLT: Gluten sensitivity - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 15:13:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Sep 2020 15:13:52
Data point term sent to Coder	System	30 Sep 2020 15:12:43
User entered 'Gluten sensitivity'	Julia Klopfer (b) (4) (b) (4)	30 Sep 2020 15:12:20

US3432016

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered 'UN UNK 2019'	Julia Klopfer (b) (4) (b) (4)	30 Sep 2020 15:12:20

US3432016

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:24:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered '0'	Julia Klopfer (b) (4) (b) (4)	30 Sep 2020 15:12:20

US3432016

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:24:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	30 Sep 2020 15:12:20

US3432016

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered empty.	Julia Klopfer (b) (4) (b) (4)	30 Sep 2020 15:12:20

US3432016

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:24:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered '0'	Julia Klopfer (b) (4) (b) (4)	30 Sep 2020 15:12:20

US3432016

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	30 Sep 2020 15:12:20

US3432016

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered '2019'	System	30 Sep 2020 15:12:20

US3432016

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 15:12:20

US3432016

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 15:12:20

US3432016

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:24:53

[Condition](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review this condition and verify if the reason for the Non-Childbearing potential is SURGICALLY STERILE instead of Post-menopausal. Please reconcile and update applicable eCRFs as appropriate. Otherwise, clarify.	Alexander Mills (b) (4)	03 Nov 2020 18:28:17
' answered with 'Post-menopausal is reason for Non-Childbearing potential' (Site from DM). User opened query 'Per DM CLR: Please review this condition and verify if the reason for the Non-Childbearing potential is SURGICALLY STERILE instead of Post-menopausal. Please reconcile and update applicable eCRFs as appropriate. Otherwise, clarify.	(b) (4), (b) (6)	28 Oct 2020 04:33:44
' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\23.0.	Coder Import (b) (4)	06 Oct 2020 14:13:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	06 Oct 2020 14:13:04
Data point term sent to Coder	System	06 Oct 2020 13:47:36
User entered 'Hysterectomy'	Jessica Cauley (b) (4)	06 Oct 2020 13:46:44
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered 'un UNK 2005'	Jessica Cauley (b) (4)	06 Oct 2020 13:46:44
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:24:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered '0'	Jessica Cauley (b) (4) (b) (4)	06 Oct 2020 13:46:44

US3432016

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:24:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered 'No (N)'	Jessica Cauley (b) (4) (b) (4)	06 Oct 2020 13:46:44

US3432016

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered 'un UNK 2005'	Jessica Cauley (b) (4) (b) (4)	06 Oct 2020 13:46:44

US3432016

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:24:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered '0'	Jessica Cauley (b) (4)	06 Oct 2020 13:46:44
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	06 Oct 2020 13:46:44

US3432016

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered '2005'	System	06 Oct 2020 13:46:44

US3432016

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered 'Jan 2005'	System	06 Oct 2020 13:46:44

US3432016

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered '2005'	System	06 Oct 2020 13:46:44

US3432016

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:24:53

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Palatal therapeutic procedures, PT: Uvulectomy, LLT: Uvulectomy - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 14:13:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	06 Oct 2020 14:13:04
Data point term sent to Coder	System	06 Oct 2020 13:47:36
User entered 'Uvula removal'	Jessica Cauley (b) (4)	06 Oct 2020 13:47:00
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered 'un UNK 1995'	Jessica Cauley (b) (4)	06 Oct 2020 13:47:00
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:24:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered '0'	Jessica Cauley (b) (4)	06 Oct 2020 13:47:00
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:24:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered 'No (N)'	Jessica Cauley (b) (4)	06 Oct 2020 13:47:00
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered 'un UNK 1995'	Jessica Cauley (b) (4)	06 Oct 2020 13:47:00
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:24:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered '0'	Jessica Cauley (b) (4)	06 Oct 2020 13:47:00
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered 'Jan 1995'	System	06 Oct 2020 13:47:00

US3432016

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered '1995'	System	06 Oct 2020 13:47:00

US3432016

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered 'Jan 1995'	System	06 Oct 2020 13:47:00

US3432016

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered '1995'	System	06 Oct 2020 13:47:00

US3432016

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:24:53

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User coded data point as SOC: Surgical and medical procedures, HLGT: Endocrine gland therapeutic procedures, HLT: Thyroid therapeutic procedures, PT: Thyroidectomy, LLT: Thyroidectomy partial - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 14:13:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 14:13:04
Data point term sent to Coder	System	06 Oct 2020 13:47:37
User entered 'Partial thyroidectomy'	Jessica Cauley (b) (4) (b) (4)	06 Oct 2020 13:47:26

US3432016

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered 'un UNK 1995'	Jessica Cauley (b) (4)	06 Oct 2020 13:47:26
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:24:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered '0'	Jessica Cauley (b) (4)	06 Oct 2020 13:47:26
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:24:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered 'No (N)'	Jessica Cauley (b) (4)	06 Oct 2020 13:47:26
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered 'un UNK 1995'	Jessica Cauley (b) (4) (b) (4)	06 Oct 2020 13:47:26

US3432016

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:24:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered '0'	Jessica Cauley (b) (4)	06 Oct 2020 13:47:26
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered 'Jan 1995'	System	06 Oct 2020 13:47:26

US3432016

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered '1995'	System	06 Oct 2020 13:47:26

US3432016

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered 'Jan 1995'	System	06 Oct 2020 13:47:26

US3432016

Folder: Screening

Form: Medical History (15)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered '1995'	System	06 Oct 2020 13:47:26

US3432016

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:24:53

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Knee replacement - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 14:13:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 14:13:06
Data point term sent to Coder	System	06 Oct 2020 13:48:40
User entered 'Knee replacement'	Jessica Cauley (b) (4) (b) (4)	06 Oct 2020 13:47:43

US3432016

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered 'un UNK 2011'	Jessica Cauley (b) (4)	06 Oct 2020 13:47:43
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:24:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered '0'	Jessica Cauley (b) (4)	06 Oct 2020 13:47:43
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:24:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered 'No (N)'	Jessica Cauley (b) (4)	06 Oct 2020 13:47:43
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered 'un UNK 2011'	Jessica Cauley (b) (4) (b) (4)	06 Oct 2020 13:47:43

US3432016

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:24:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered '0'	Jessica Cauley (b) (4)	06 Oct 2020 13:47:43
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered 'Jan 2011'	System	06 Oct 2020 13:47:43

US3432016

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered '2011'	System	06 Oct 2020 13:47:43

US3432016

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered 'Jan 2011'	System	06 Oct 2020 13:47:43

US3432016

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered '2011'	System	06 Oct 2020 13:47:43

US3432016

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:24:53

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Hip arthroplasty, LLT: Hip replacement - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 14:13:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 14:13:06
Data point term sent to Coder	System	06 Oct 2020 13:48:40
User entered 'hip replacement'	Jessica Cauley (b) (4) (b) (4)	06 Oct 2020 13:48:00

US3432016

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered 'un UNK 2017'	Jessica Cauley (b) (4)	06 Oct 2020 13:48:00
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:24:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered '0'	Jessica Cauley (b) (4)	06 Oct 2020 13:48:00
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:24:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered 'No (N)'	Jessica Cauley (b) (4)	06 Oct 2020 13:48:00
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered 'un UNK 2017'	Jessica Cauley (b) (4)	06 Oct 2020 13:48:00
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:24:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered '0'	Jessica Cauley (b) (4)	06 Oct 2020 13:48:00
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	06 Oct 2020 13:48:00

US3432016

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered '2017'	System	06 Oct 2020 13:48:00

US3432016

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	06 Oct 2020 13:48:00

US3432016

Folder: Screening

Form: Medical History (17)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered '2017'	System	06 Oct 2020 13:48:00

US3432016

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:24:53

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Tonsillectomy, LLT: Tonsillectomy - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 14:13:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	06 Oct 2020 14:13:06
Data point term sent to Coder	System	06 Oct 2020 13:48:40
User entered 'tonsillectomy'	Jessica Cauley (b) (4)	06 Oct 2020 13:48:21
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered 'un UNK 1960'	Jessica Cauley (b) (4)	06 Oct 2020 13:48:21

US3432016

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:24:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered '0'	Jessica Cauley (b) (4)	06 Oct 2020 13:48:21
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:24:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered 'No (N)'	Jessica Cauley (b) (4)	06 Oct 2020 13:48:21
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered 'un UNK 1960'	Jessica Cauley (b) (4)	06 Oct 2020 13:48:21
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:24:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered '0'	Jessica Cauley (b) (4)	06 Oct 2020 13:48:21
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered 'Jan 1960'	System	06 Oct 2020 13:48:21

US3432016

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered '1960'	System	06 Oct 2020 13:48:21

US3432016

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered 'Jan 1960'	System	06 Oct 2020 13:48:21

US3432016

Folder: Screening

Form: Medical History (18)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered '1960'	System	06 Oct 2020 13:48:21

US3432016

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:24:53

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Cardiac therapeutic procedures NEC, PT: Atrial appendage closure, LLT: Atrial appendage closure - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Nov 2020 14:35:34
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Nov 2020 14:35:34
Data point term sent to Coder	System	21 Oct 2020 23:56:25
User closed query 'DM-Coding: Please split diagnosis and procedure to report each event separately' (Site from System).	System	21 Oct 2020 23:55:56
Query 'DM-Coding: Please split diagnosis and procedure to report each event separately' answered with 'Atrial Fibrillation is listed in a separate log-line.This procedure was for that earlier diagnosis.' (Site from System).	(b) (4), (b) (6) (b) (4)	21 Oct 2020 23:55:56
User opened query 'DM-Coding: Please split diagnosis and procedure to report each event separately' (Site from System).	Coder Import (b) (4) (b) (4)	09 Oct 2020 09:22:15
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	06 Oct 2020 17:01:40
Data point term sent to Coder	System	06 Oct 2020 13:49:42
User entered 'Watchman procedure for Atrial fibrillation'	Jessica Cauley (b) (4) (b) (4)	06 Oct 2020 13:48:49

US3432016

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered 'un Nov 2019'	Jessica Cauley (b) (4)	06 Oct 2020 13:48:49

US3432016

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:24:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered '0'	Jessica Cauley (b) (4)	06 Oct 2020 13:48:49
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:24:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered 'No (N)'	Jessica Cauley (b) (4)	06 Oct 2020 13:48:49
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered 'un Nov 2019'	Jessica Cauley (b) (4)	06 Oct 2020 13:48:49
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:24:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered '0'	Jessica Cauley (b) (4)	06 Oct 2020 13:48:49
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered 'Nov 2019'	System	06 Oct 2020 13:48:49

US3432016

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered '2019'	System	06 Oct 2020 13:48:49

US3432016

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered 'Nov 2019'	System	06 Oct 2020 13:48:49

US3432016

Folder: Screening

Form: Medical History (19)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered '2019'	System	06 Oct 2020 13:48:49

US3432016

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:24:53

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Peripheral nerve therapeutic procedures, PT: Carpal tunnel decompression, LLT: Carpal tunnel release - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 14:13:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 14:13:09
Data point term sent to Coder	System	06 Oct 2020 13:49:42
User entered 'Carpal tunnel surgery'	Jessica Cauley (b) (4) (b) (4)	06 Oct 2020 13:49:13

US3432016

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered 'un UNK 2017'	Jessica Cauley (b) (4)	06 Oct 2020 13:49:13
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:24:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered '0'	Jessica Cauley (b) (4)	06 Oct 2020 13:49:13
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:24:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered 'No (N)'	Jessica Cauley (b) (4)	06 Oct 2020 13:49:13
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered 'un UNK 2017'	Jessica Cauley (b) (4)	06 Oct 2020 13:49:13
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:24:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered '0'	Jessica Cauley (b) (4)	06 Oct 2020 13:49:13
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	06 Oct 2020 13:49:13

US3432016

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered '2017'	System	06 Oct 2020 13:49:13

US3432016

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	06 Oct 2020 13:49:13

US3432016

Folder: Screening

Form: Medical History (20)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered '2017'	System	06 Oct 2020 13:49:13

US3432016

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:24:53

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User coded data point as SOC: Surgical and medical procedures, HLGT: Soft tissue therapeutic procedures, HLT: Tendon therapeutic procedures, PT: Tendon sheath incision, LLT: Trigger finger release - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 14:13:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 14:13:09
Data point term sent to Coder	System	06 Oct 2020 13:49:42
User entered 'trigger finger surgery'	Jessica Cauley (b) (4)	06 Oct 2020 13:49:29
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered 'un UNK 2018'	Jessica Cauley (b) (4) (b) (4)	06 Oct 2020 13:49:29

US3432016

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:24:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered '0'	Jessica Cauley (b) (4)	06 Oct 2020 13:49:29
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:24:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered 'No (N)'	Jessica Cauley (b) (4)	06 Oct 2020 13:49:29
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered 'un UNK 2018'	Jessica Cauley (b) (4)	06 Oct 2020 13:49:29
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:24:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered '0'	Jessica Cauley (b) (4)	06 Oct 2020 13:49:29
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	06 Oct 2020 13:49:29

US3432016

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered '2018'	System	06 Oct 2020 13:49:29

US3432016

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	06 Oct 2020 13:49:29

US3432016

Folder: Screening

Form: Medical History (21)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered '2018'	System	06 Oct 2020 13:49:29

US3432016

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:24:53

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
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)	06 Oct 2020 14:13:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Oct 2020 14:13:11
Data point term sent to Coder	System	06 Oct 2020 13:50:45
User entered 'cataract surgery'	Jessica Cauley (b) (4) (b) (4)	06 Oct 2020 13:49:52

US3432016

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered 'un UNK 2015'	Jessica Cauley (b) (4)	06 Oct 2020 13:49:52
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:24:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered '0'	Jessica Cauley (b) (4)	06 Oct 2020 13:49:52
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:24:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered 'No (N)'	Jessica Cauley (b) (4)	06 Oct 2020 13:49:52
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered 'un UNK 2015'	Jessica Cauley (b) (4) (b) (4)	06 Oct 2020 13:49:52

US3432016

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:24:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered '0'	Jessica Cauley (b) (4)	06 Oct 2020 13:49:52
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	06 Oct 2020 13:49:52

US3432016

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered '2015'	System	06 Oct 2020 13:49:52

US3432016

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	06 Oct 2020 13:49:52

US3432016

Folder: Screening

Form: Medical History (22)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered '2015'	System	06 Oct 2020 13:49:52

US3432016

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:24:53

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 18:27:01
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'Will follow up with participant at next scheduled appointment' (Site from DM).	Alexander Mills (b) (4)	03 Nov 2020 18:41:36
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 04:34:25
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\23.0.	Coder Import (b) (4)	06 Oct 2020 14:13:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	06 Oct 2020 14:13:12
Data point term sent to Coder	System	06 Oct 2020 13:50:43
User entered 'cholecystectomy'	Jessica Cauley (b) (4)	06 Oct 2020 13:50:09

US3432016

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered 'un UNK 2018'	Jessica Cauley (b) (4)	06 Oct 2020 13:50:09
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:24:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered '0'	Jessica Cauley (b) (4)	06 Oct 2020 13:50:09
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:24:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered 'No (N)'	Jessica Cauley (b) (4)	06 Oct 2020 13:50:09
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered 'un UNK 2018'	Jessica Cauley (b) (4)	06 Oct 2020 13:50:09
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:24:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:01:40
User entered '0'	Jessica Cauley (b) (4)	06 Oct 2020 13:50:09
	(b) (4)	

US3432016

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	06 Oct 2020 13:50:09

US3432016

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered '2018'	System	06 Oct 2020 13:50:09

US3432016

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	06 Oct 2020 13:50:09

US3432016

Folder: Screening

Form: Medical History (23)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered '2018'	System	06 Oct 2020 13:50:09

US3432016

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 09:24:53

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:02:28
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: GERD - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Oct 2020 14:00:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Oct 2020 14:00:36
Data point term sent to Coder	System	24 Oct 2020 13:59:08
User entered 'GERD'	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:59:02
DataPoint activated with code reason code Data required.	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:58:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Oct 2020 23:59:30

US3432016

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:02:28
User entered 'un UNK 2018'	Bruce Bausk (b) (4)	24 Oct 2020 13:59:02
DataPoint activated with code reason code Data required.	Bruce Bausk (b) (4)	24 Oct 2020 13:58:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Oct 2020 23:59:30

US3432016

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 09:24:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:02:28
User entered '0'	Bruce Bausk (b) (4)	24 Oct 2020 13:59:02
DataPoint activated with code reason code Data required.	Bruce Bausk (b) (4)	24 Oct 2020 13:58:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Oct 2020 23:59:30

US3432016

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 09:24:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:02:28
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	24 Oct 2020 13:59:02
DataPoint activated with code reason code Data required.	Bruce Bausk (b) (4)	24 Oct 2020 13:58:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Oct 2020 23:59:30

US3432016

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:02:28
User entered empty.	Bruce Bausk (b) (4)	24 Oct 2020 13:59:02
DataPoint activated with code reason code Data required.	Bruce Bausk (b) (4)	24 Oct 2020 13:58:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Oct 2020 23:59:30

US3432016

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 09:24:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:02:28
User entered '0'	Bruce Bausk (b) (4)	24 Oct 2020 13:59:02
DataPoint activated with code reason code Data required.	Bruce Bausk (b) (4)	24 Oct 2020 13:58:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	21 Oct 2020 23:59:30

US3432016

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	24 Oct 2020 13:59:02
DataPoint activated with code reason code Data required.	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:58:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6) (b) (4)	21 Oct 2020 23:59:30

US3432016

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered '2018'	System	24 Oct 2020 13:59:02
DataPoint activated with code reason code Data required.	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:58:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6) (b) (4)	21 Oct 2020 23:59:30

US3432016

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered empty.	System	24 Oct 2020 13:59:02
DataPoint activated with code reason code Data required.	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:58:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6) (b) (4)	21 Oct 2020 23:59:30

US3432016

Folder: Screening

Form: Medical History (24)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered empty.	System	24 Oct 2020 13:59:02
DataPoint activated with code reason code Data required.	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:58:43
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6) (b) (4)	21 Oct 2020 23:59:30

US3432016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:13:59
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:03:15

US3432016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:13:59
User entered '05 Aug 2020'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:03:15

US3432016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:13:59
User entered '08:31'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:03:15

US3432016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered '05 Aug 2020 08:31'	System	05 Aug 2020 19:03:15

US3432016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:13:59
User entered '161' cm	Julia Klopfer (b) (4)	05 Aug 2020 19:03:15
DataPoint set to visible.	(b) (4) System	05 Aug 2020 13:25:46

US3432016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:13:59
User entered '93.2' kg	Julia Klopfer (b) (4)	05 Aug 2020 19:03:15
DataPoint set to visible.	(b) (4) System	05 Aug 2020 13:25:46

US3432016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:53

BMI (xxx.x)

Audit	User	Time (GMT)
Amendment Manager: User entered '35.95540'	System	16 Sep 2020 23:43:33
User entered '36.0'	System	05 Aug 2020 19:03:15
DataPoint set to visible.	System	05 Aug 2020 13:25:46

US3432016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:53

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	05 Aug 2020 19:03:15
DataPoint set to visible.	System	05 Aug 2020 13:25:46

US3432016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:53

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Un-verified.	Megan Powell (b) (4)	13 Aug 2020 19:50:13
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Megan Powell (b) (4)	13 Aug 2020 19:50:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Aug 2020 18:13:59
User entered '36.9' C	Julia Klopfer (b) (4)	05 Aug 2020 19:03:15
	(b) (4)	

US3432016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:53

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:04:46
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 18:17:44
Query 'Data is required. Please provide.' answered with 'no its not' (Site from System).	Megan Powell (b) (4)	13 Aug 2020 19:50:19
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	13 Aug 2020 19:50:13
DataPoint Un-verified.	System	13 Aug 2020 19:50:13
	Megan Powell (b) (4)	13 Aug 2020 19:50:13
User entered empty; reason for change Per Query Resolution	(b) (4)	13 Aug 2020 19:50:13
DataPoint Verified.	Megan Powell (b) (4)	13 Aug 2020 19:50:13
	(b) (4)	11 Aug 2020 18:13:59
User entered 'Oral (Oral)'	(b) (4), (b) (6)	11 Aug 2020 18:13:59
	(b) (4)	05 Aug 2020 19:03:15
	Julia Klopfer (b) (4)	05 Aug 2020 19:03:15
	(b) (4)	

US3432016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:53

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:13:59
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:03:15

US3432016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:04:49
DataPoint Un-verified.	Megan Powell (b) (4)	13 Aug 2020 19:50:13
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	13 Aug 2020 19:50:13
DataPoint Verified.	Megan Powell (b) (4)	13 Aug 2020 19:50:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:13:59
	(b) (4)	
User entered '88'	Julia Klopfer (b) (4)	05 Aug 2020 19:03:15
	(b) (4)	

US3432016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:53

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Aug 2020 19:03:15

US3432016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:04:51
DataPoint Un-verified.	Megan Powell (b) (4)	13 Aug 2020 19:50:13
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	13 Aug 2020 19:50:13
DataPoint Verified.	Megan Powell (b) (4)	13 Aug 2020 19:50:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:13:59
User entered '16'	(b) (4)	
	Julia Klopfer (b) (4)	05 Aug 2020 19:03:15
	(b) (4)	

US3432016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Aug 2020 19:03:15

US3432016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:04:52
DataPoint Un-verified.	Megan Powell (b) (4)	13 Aug 2020 19:50:13
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	13 Aug 2020 19:50:13
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:13:59
User entered '115'	Julia Klopfer (b) (4)	05 Aug 2020 19:03:15
	(b) (4)	

US3432016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Aug 2020 19:03:15

US3432016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:53

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:04:54
DataPoint Un-verified.	Megan Powell (b) (4)	13 Aug 2020 19:50:13
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	13 Aug 2020 19:50:13
DataPoint Verified.	Megan Powell (b) (4)	13 Aug 2020 19:50:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:13:59
	(b) (4)	
User entered '68'	Julia Klopfer (b) (4)	05 Aug 2020 19:03:15
	(b) (4)	

US3432016

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Aug 2020 19:03:15

US3432016

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:24:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:14:20
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:03:42

US3432016

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:24:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	08 Sep 2020 03:36:56
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	02 Sep 2020 14:20:24
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:14:22
User entered '05 Aug 2020'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:03:42

US3432016

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:24:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:00:34
User entered '05 Aug 2020'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:05:28

US3432016

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:24:53

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:00:34
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:05:28

US3432016

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:24:53

If No, what is the reason?

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 07:17:32
User opened query 'Per CDM re-query: Per Sponsor request, supporting documentation for Post-Menopausal should be entered in MH. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 07:17:31
User closed query 'Post-menopausal has not been entered, however date of last menstruation is provided, or Date of last menstruation unknown is checked. Please correct.' (Site from System).	System	03 Nov 2020 18:27:20
User entered 'Post-menopausal (POST-MENOPAUSAL)' reason for change: Data Entry Error	Alexander Mills (b) (4)	03 Nov 2020 18:27:20
User opened query 'Post-menopausal has not been entered, however date of last menstruation is provided, or Date of last menstruation unknown is checked. Please correct.' (Site from System).	System	03 Nov 2020 18:27:07
DataPoint Un-verified.	Alexander Mills (b) (4)	03 Nov 2020 18:27:07
User entered 'Surgically sterile (SURGICALLY STERILE)' reason for change: Data Entry Error	Alexander Mills (b) (4)	03 Nov 2020 18:27:07
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' answered with 'This is not a medical condition since it is a natural process of aging.' (Site from DM).	Jun Bai Park Chang (b) (4)	08 Oct 2020 16:20:03
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 06:44:52
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:00:34
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Julia Klopfer (b) (4)	05 Aug 2020 19:05:28

US3432016

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:24:53

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:00:34
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:05:28

US3432016

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User closed query 'Surgically sterile been entered, however date of surgery is missing. Please provide.' (Site from System).	System	03 Nov 2020 18:27:20
User opened query 'Surgically sterile been entered, however date of surgery is missing. Please provide.' (Site from System).	System	03 Nov 2020 18:27:07
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:00:34
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:05:28

US3432016

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:24:53

Date of surgery unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:00:34
User entered '0'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:05:28

US3432016

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:24:53

If Post-menopausal, date of last menstruation (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:00:34
User entered 'UN UNK 2005'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:05:28

US3432016

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:24:53

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:00:34
User entered '0'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:05:28

US3432016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:53

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 17:44:57
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:08:48

US3432016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:53

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 17:44:57
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:08:48

US3432016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:53

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 17:44:57
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:08:48

US3432016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:53

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 17:44:57
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:08:48

US3432016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:53

[Warehouse shipping and fulfillment centers](#) and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 17:44:57
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:08:48

US3432016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:53

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 17:44:57
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:08:48

US3432016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:53

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 17:44:57
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:08:48

US3432016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:53

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 17:44:57
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:08:48

US3432016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:53

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 17:44:57
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:08:48

US3432016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:53

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 17:44:57
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:08:48

US3432016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:53

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 17:44:57
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:08:48

US3432016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:53

[Other](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 17:44:57
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:08:48

US3432016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:53

[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 17:44:57
User entered 'Retired'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:08:48

US3432016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:53

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:08:48

US3432016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:53

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 17:44:57
User entered '0'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:08:48

US3432016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 17:44:57
User entered '0'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:08:48

US3432016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:53

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 17:44:57
User entered '1'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:08:48

US3432016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:53

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 17:44:57
User entered '0'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:08:48

US3432016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:53

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 17:44:57
User entered '0'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:08:48

US3432016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:53

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:08:48

US3432016

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:24:53

[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 17:44:57
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:08:48

US3432016

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:24:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:15:03
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:19:07

US3432016

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:15:03
User entered '05 Aug 2020'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:19:07

US3432016

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:15:03
User entered 'Clinic (Clinic)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:19:07

US3432016

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:24:53

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	05 Aug 2020 19:19:07

US3432016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 17:51:35
User entered '05 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 13:04:26

US3432016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:24:53

[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 02:10:28
Amendment Manager: Data point set to conformant. DataPoint Verified.	System	21 Aug 2020 02:10:28
	(b) (4), (b) (6)	11 Aug 2020 17:51:37
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	05 Aug 2020 13:04:26
User entered '184650' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 13:04:26

US3432016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:24:53

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 17:51:39
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 13:04:26

US3432016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:24:53

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 17:51:44
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:20:04

US3432016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:24:53

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 12:00:24
User closed query 'medical history shows subjects has atrial fibrillation, bradycardia, hypertension. Please review and confirm if this will be marked as "yes" (Site from CRA).	(b) (4), (b) (6)	14 Sep 2020 12:00:20
Query 'medical history shows subjects has atrial fibrillation, bradycardia, hypertension. Please review and confirm if this will be marked as "yes" answered with 'not significant cardiac disease' (Site from CRA).	Monica Feeley (b) (4)	27 Aug 2020 11:16:39
User opened query 'medical history shows subjects has atrial fibrillation, bradycardia, hypertension. Please review and confirm if this will be marked as "yes" (Site from CRA).	(b) (4), (b) (6)	11 Aug 2020 17:53:15
User entered 'No (N)'	Julia Klopfer (b) (4)	05 Aug 2020 19:20:04

US3432016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:24:53

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 17:55:02
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:20:04

US3432016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:24:53

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 17:55:04
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:20:04

US3432016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:24:53

[Liver Disease](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 17:55:05
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:20:04

US3432016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:24:53

[Height](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:18:31
User entered missing code ND - Not Done.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:25:43

US3432016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:24:53

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:18:31
User entered missing code ND - Not Done.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:25:43

US3432016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:24:53

[Height](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:18:31
User entered missing code ND - Not Done.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:25:43

US3432016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:24:53

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:18:31
User entered missing code ND - Not Done.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:25:43

US3432016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:53

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:25:43

US3432016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:18:31
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:25:43

US3432016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:18:31
User entered '05 Aug 2020'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:25:43

US3432016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:18:31
User entered '08:31'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:25:43

US3432016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered '05 Aug 2020 08:31'	System	05 Aug 2020 19:25:43

US3432016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:53

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:18:31
User entered '36.9' C	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:25:43

US3432016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:53

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:18:31
User entered 'Oral (Oral)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:25:43

US3432016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:53

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:18:31
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:25:43

US3432016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:18:31
User entered '88'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:25:43

US3432016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:53

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Aug 2020 19:25:43

US3432016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:18:31
User entered '16'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:25:43

US3432016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Aug 2020 19:25:43

US3432016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:18:31
User entered '115'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:25:43

US3432016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Aug 2020 19:25:43

US3432016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:53

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:18:31
User entered '68'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:25:43

US3432016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Aug 2020 19:25:43

US3432016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:24:53

[Height](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:18:31
User entered missing code ND - Not Done.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:25:43

US3432016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:24:53

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:18:31
User entered missing code ND - Not Done.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:25:43

US3432016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:53

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:25:43

US3432016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:18:31
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:25:43

US3432016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:18:31
User entered '05 Aug 2020'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:25:43

US3432016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System). DataPoint Verified.	(b) (4), (b) (6)	17 Aug 2020 08:54:33
	(b) (4), (b) (6)	11 Aug 2020 18:18:31
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'per protocol post-dose vitals can be obtained 30 minute post dosage' (Site from System).	Phoebe Cunningham (b) (4)	08 Aug 2020 16:15:05
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		05 Aug 2020 19:25:43
User entered '10:29'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:25:43

US3432016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered '05 Aug 2020 10:29'	System	05 Aug 2020 19:25:43

US3432016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:53

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:18:31
User entered '37' C	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:25:43

US3432016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:53

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:18:31
User entered 'Oral (Oral)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:25:43

US3432016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:53

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:18:31
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:25:43

US3432016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:18:31
User entered '87'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:25:43

US3432016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:53

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Aug 2020 19:25:43

US3432016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:18:31
User entered '16'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:25:43

US3432016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Aug 2020 19:25:43

US3432016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:18:31
User entered '121'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:25:43

US3432016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Aug 2020 19:25:43

US3432016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:18:31
User entered '75'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:25:43

US3432016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Aug 2020 19:25:43

US3432016

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:24:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:17:02
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:27:40

US3432016

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:24:53

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:17:02
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:27:40

US3432016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:24:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:16:36
User entered 'Yes (Y)'	Natalie Izaguirre (b) (4)	05 Aug 2020 14:09:34

US3432016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:24:53

[If No, reason not given](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:16:36
User entered empty.	Natalie Izaguirre (b) (4)	05 Aug 2020 14:09:34

US3432016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:16:36
User entered empty.	Natalie Izaguirre (b) (4)	05 Aug 2020 14:09:34

US3432016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:24:53

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	05 Aug 2020 14:09:34

US3432016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:24:53

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:16:36
User entered '05 Aug 2020'	Natalie Izaguirre (b) (4)	05 Aug 2020 14:09:34

US3432016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:24:53

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:16:36
User entered '09:59'	Natalie Izaguirre (b) (4)	05 Aug 2020 14:09:34

US3432016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:24:53

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 09:59'	System	05 Aug 2020 14:09:34

US3432016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:24:53

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:16:36
User entered 'Left Arm (LEFT ARM)'	Natalie Izaguirre (b) (4)	05 Aug 2020 14:09:34

US3432016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:24:53

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:16:36
User entered 'ONCE'	System	05 Aug 2020 14:09:34

US3432016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:24:53

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	05 Aug 2020 14:09:34

US3432016

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:24:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
User closed query 'Per IMMUNO Lab Recon: it appears a sample was collected on 05AUG2020; however, it has not been received by GCL. Please clarify and, if shipped, please provide tracking detail' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 09:30:37
Query 'Per IMMUNO Lab Recon: it appears a sample was collected on 05AUG2020; however, it has not been received by GCL. Please clarify and, if shipped, please provide tracking detail' answered with 'Checked in Preclarus Portal and we got report saying that they did receive samples collected on 05AUG2020.' (Site from DM).	Jun Bai Park Chang (b) (4)	07 Oct 2020 13:36:19
User opened query 'Per IMMUNO Lab Recon: it appears a sample was collected on 05AUG2020; however, it has not been received by GCL. Please clarify and, if shipped, please provide tracking detail' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 02:55:24
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:19:02
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:28:38

US3432016

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:24:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:19:02
User entered '05 Aug 2020'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:28:38

US3432016

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:24:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:19:02
User entered '09:09'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:28:38

US3432016

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:24:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 09:09'	System	05 Aug 2020 19:28:38

US3432016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:24:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:19:33
User entered '05 Aug 2020'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:29:33

US3432016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:24:53

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:29:33

US3432016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:24:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:19:33
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:29:33

US3432016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:24:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:19:33
User entered '09:15'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:29:33

US3432016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:24:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 09:15'	System	05 Aug 2020 19:29:33

US3432016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:24:53

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:29:33

US3432016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:24:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:19:33
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:29:33

US3432016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:24:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:19:33
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:29:33

US3432016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:24:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 19:29:33

US3432016

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:24:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:29:51

US3432016

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:24:53

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 19:29:51

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 14:09:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-05T10:31:04', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '71ff5c6e-8343-43af-aca0-50c3e224ccc7'	System	05 Aug 2020 14:31:49
User entered 'Yes (Y)'	System	05 Aug 2020 14:31:49

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-05T10:31:27', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '71ff5c6e-8343-43af-aca0-50c3e224ccc7'	System	05 Aug 2020 14:31:49
User entered '98.6'	System	05 Aug 2020 14:31:49

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-05T10:31:32', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '71ff5c6e-8343-43af-aca0-50c3e224ccc7'	System	05 Aug 2020 14:31:49
User entered 'No (N)'	System	05 Aug 2020 14:31:49

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-05T10:31:44', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '71ff5c6e-8343-43af-aca0-50c3e224ccc7'	System	05 Aug 2020 14:31:49
User entered '05 Aug 2020 10:31'	System	05 Aug 2020 14:31:49

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 10:19'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 12:49'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 14:09:34
User entered 'Day 1, after vaccination (at home)'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-05T16:57:32', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'ae950be3-5cdc-48bd-87ec-a1efe4ff668c'	System	05 Aug 2020 20:58:49
User entered 'Yes (Y)'	System	05 Aug 2020 20:58:49

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-05T16:58:32', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'ae950be3-5cdc-48bd-87ec-a1efe4ff668c'	System	05 Aug 2020 20:58:49
User entered '98.5'	System	05 Aug 2020 20:58:49

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-05T16:58:36', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'ae950be3-5cdc-48bd-87ec-a1efe4ff668c'	System	05 Aug 2020 20:58:49
User entered 'No (N)'	System	05 Aug 2020 20:58:49

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-05T16:58:46', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'ae950be3-5cdc-48bd-87ec-a1efe4ff668c'	System	05 Aug 2020 20:58:49
User entered '05 Aug 2020 16:58'	System	05 Aug 2020 20:58:49

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 13:44'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:59'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 14:09:34
User entered 'Day 2'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:24:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-06T16:57:44', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '13d34e55-2f8f-4c6b-ad0f-747c41bd9f38'	System	06 Aug 2020 20:58:50
User entered 'Yes (Y)'	System	06 Aug 2020 20:58:50

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:24:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-06T16:58:31', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '13d34e55-2f8f-4c6b-ad0f-747c41bd9f38'	System	06 Aug 2020 20:58:50
User entered '97.7'	System	06 Aug 2020 20:58:50

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-06T16:58:36', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '13d34e55-2f8f-4c6b-ad0f-747c41bd9f38'	System	06 Aug 2020 20:58:50
User entered 'No (N)'	System	06 Aug 2020 20:58:50

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:24:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-06T16:58:46', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '13d34e55-2f8f-4c6b-ad0f-747c41bd9f38'	System	06 Aug 2020 20:58:50
User entered '06 Aug 2020 16:58'	System	06 Aug 2020 20:58:50

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:24:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 12:00'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:24:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 14:09:34
User entered 'Day 3'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:24:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-07T15:11:25', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'dd75e064-43e8-4780-94eb-a444252e51a6'	System	07 Aug 2020 19:11:43
User entered 'Yes (Y)'	System	07 Aug 2020 19:11:43

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:24:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-07T15:11:32', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'dd75e064-43e8-4780-94eb-a444252e51a6'	System	07 Aug 2020 19:11:43
User entered '97.9'	System	07 Aug 2020 19:11:43

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-07T15:11:35', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'dd75e064-43e8-4780-94eb-a444252e51a6'	System	07 Aug 2020 19:11:43
User entered 'No (N)'	System	07 Aug 2020 19:11:43

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:24:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-07T15:11:42', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'dd75e064-43e8-4780-94eb-a444252e51a6'	System	07 Aug 2020 19:11:43
User entered '07 Aug 2020 15:11'	System	07 Aug 2020 19:11:43

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:24:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:00'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:24:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 14:09:34
User entered 'Day 4'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:24:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-08T16:13:44', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '7ecfa02a-bb52-4525-86c1-67b2a7d1ad46'	System	08 Aug 2020 20:14:01
User entered 'Yes (Y)'	System	08 Aug 2020 20:14:01

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:24:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-08T16:13:48', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '7ecfa02a-bb52-4525-86c1-67b2a7d1ad46'	System	08 Aug 2020 20:14:01
User entered '97.8'	System	08 Aug 2020 20:14:01

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-08T16:13:51', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '7ecfa02a-bb52-4525-86c1-67b2a7d1ad46'	System	08 Aug 2020 20:14:01
User entered 'No (N)'	System	08 Aug 2020 20:14:01

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:24:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-08T16:13:59', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '7ecfa02a-bb52-4525-86c1-67b2a7d1ad46'	System	08 Aug 2020 20:14:01
User entered '08 Aug 2020 16:13'	System	08 Aug 2020 20:14:01

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:24:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:24:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 14:09:34
User entered 'Day 5'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:24:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-09T16:59:46', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '61c59861-c350-460b-bb8f-0edad66cc8bc'	System	09 Aug 2020 21:00:15
User entered 'Yes (Y)'	System	09 Aug 2020 21:00:15

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:24:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-09T16:59:52', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '61c59861-c350-460b-bb8f-0edad66cc8bc'	System	09 Aug 2020 21:00:15
User entered '99.1'	System	09 Aug 2020 21:00:15

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-09T17:00:01', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '61c59861-c350-460b-bb8f-0edad66cc8bc'	System	09 Aug 2020 21:00:15
User entered 'No (N)'	System	09 Aug 2020 21:00:15

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:24:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-09T17:00:11', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '61c59861-c350-460b-bb8f-0edad66cc8bc'	System	09 Aug 2020 21:00:15
User entered '09 Aug 2020 17:00'	System	09 Aug 2020 21:00:15

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:24:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:24:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 14:09:34
User entered 'Day 6'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:24:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-10T16:11:49', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '1ff20681-0fce-4f84-8283-935d4c664c59'	System	10 Aug 2020 20:12:11
User entered 'Yes (Y)'	System	10 Aug 2020 20:12:11

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:24:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-10T16:11:56', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '1ff20681-0fce-4f84-8283-935d4c664c59'	System	10 Aug 2020 20:12:11
User entered '98.5'	System	10 Aug 2020 20:12:11

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-10T16:11:59', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '1ff20681-0fce-4f84-8283-935d4c664c59'	System	10 Aug 2020 20:12:11
User entered 'No (N)'	System	10 Aug 2020 20:12:11

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:24:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-10T16:12:06', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '1ff20681-0fce-4f84-8283-935d4c664c59'	System	10 Aug 2020 20:12:11
User entered '10 Aug 2020 16:12'	System	10 Aug 2020 20:12:11

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:24:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:24:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 14:09:34
User entered 'Day 7'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:24:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-11T17:52:57', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '92688d96-2988-4f75-bc58-34542b563f61'	System	11 Aug 2020 21:53:21
User entered 'Yes (Y)'	System	11 Aug 2020 21:53:21

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:24:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-11T17:53:04', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '92688d96-2988-4f75-bc58-34542b563f61'	System	11 Aug 2020 21:53:21
User entered '98.4'	System	11 Aug 2020 21:53:21

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-11T17:53:07', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '92688d96-2988-4f75-bc58-34542b563f61'	System	11 Aug 2020 21:53:21
User entered 'No (N)'	System	11 Aug 2020 21:53:21

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:24:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-11T17:53:14', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '92688d96-2988-4f75-bc58-34542b563f61'	System	11 Aug 2020 21:53:21
User entered '11 Aug 2020 17:53'	System	11 Aug 2020 21:53:21

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:24:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:24:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 14:09:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

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 (b99ae654c582cef3)', Time: '2020-08-05T10:32:00', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '054bae88-5b25-4d1d-88b5-ae3d1ead02f5'	System	05 Aug 2020 14:32:29
User entered 'None (1)'	System	05 Aug 2020 14:32:29

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-05T10:32:08', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '054bae88-5b25-4d1d-88b5-ae3d1ead02f5'	System	05 Aug 2020 14:32:29
User entered 'No (N)'	System	05 Aug 2020 14:32:29

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-05T10:32:13', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '054bae88-5b25-4d1d-88b5-ae3d1ead02f5'	System	05 Aug 2020 14:32:29
User entered 'No (N)'	System	05 Aug 2020 14:32:29

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

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 (b99ae654c582cef3)', Time: '2020-08-05T10:32:21', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '054bae88-5b25-4d1d-88b5-ae3d1ead02f5'	System	05 Aug 2020 14:32:29
User entered 'None (1)'	System	05 Aug 2020 14:32:29

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-05T10:32:27', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '054bae88-5b25-4d1d-88b5-ae3d1ead02f5'	System	05 Aug 2020 14:32:29
User entered '05 Aug 2020 10:32'	System	05 Aug 2020 14:32:29

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 10:19'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 12:49'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 14:09:34
User entered 'Day 1, after vaccination (at home)'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

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 (b99ae654c582cef3)', Time: '2020-08-05T16:59:02', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '490cecdb-c274-4056-9163-5e6c9db2beee'	System	05 Aug 2020 20:59:32
User entered 'None (1)'	System	05 Aug 2020 20:59:32

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-05T16:59:04', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '490cecdb-c274-4056-9163-5e6c9db2beee'	System	05 Aug 2020 20:59:32
User entered 'No (N)'	System	05 Aug 2020 20:59:32

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-05T16:59:13', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '490cecdb-c274-4056-9163-5e6c9db2beee'	System	05 Aug 2020 20:59:32
User entered 'No (N)'	System	05 Aug 2020 20:59:32

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

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 (b99ae654c582cef3)', Time: '2020-08-05T16:59:21', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '490cecdb-c274-4056-9163-5e6c9db2beee'	System	05 Aug 2020 20:59:32
User entered 'None (1)'	System	05 Aug 2020 20:59:32

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-05T16:59:28', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '490cecdb-c274-4056-9163-5e6c9db2beee'	System	05 Aug 2020 20:59:32
User entered '05 Aug 2020 16:59'	System	05 Aug 2020 20:59:32

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 13:44'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:59'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 14:09:34
User entered 'Day 2'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:24:53

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 (b99ae654c582cef3)', Time: '2020-08-06T16:59:00', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'f612413d-3465-4afa-8bd2-a5521519f418'	System	06 Aug 2020 21:00:12
User entered 'Does not interfere with activity (2)'	System	06 Aug 2020 21:00:12

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:24:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-06T16:59:11', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'f612413d-3465-4afa-8bd2-a5521519f418'	System	06 Aug 2020 21:00:12
User entered 'No (N)'	System	06 Aug 2020 21:00:12

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-06T16:59:51', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'f612413d-3465-4afa-8bd2-a5521519f418'	System	06 Aug 2020 21:00:12
User entered 'No (N)'	System	06 Aug 2020 21:00:12

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:24:53

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 (b99ae654c582cef3)', Time: '2020-08-06T16:59:59', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'f612413d-3465-4afa-8bd2-a5521519f418'	System	06 Aug 2020 21:00:12
User entered 'None (1)'	System	06 Aug 2020 21:00:12

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:24:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-06T17:00:08', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'f612413d-3465-4afa-8bd2-a5521519f418'	System	06 Aug 2020 21:00:12
User entered '06 Aug 2020 17:00'	System	06 Aug 2020 21:00:12

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:24:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 12:00'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:24:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 14:09:34
User entered 'Day 3'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:24:53

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 (b99ae654c582cef3)', Time: '2020-08-07T15:11:52', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '8aec9276-186a-4e61-9ceb-262f407f2c70'	System	07 Aug 2020 19:12:24
User entered 'Does not interfere with activity (2)'	System	07 Aug 2020 19:12:24

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:24:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-07T15:11:55', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '8aec9276-186a-4e61-9ceb-262f407f2c70'	System	07 Aug 2020 19:12:24
User entered 'No (N)'	System	07 Aug 2020 19:12:24

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-07T15:12:07', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '8aec9276-186a-4e61-9ceb-262f407f2c70'	System	07 Aug 2020 19:12:24
User entered 'No (N)'	System	07 Aug 2020 19:12:24

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:24:53

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 (b99ae654c582cef3)', Time: '2020-08-07T15:12:15', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '8aec9276-186a-4e61-9ceb-262f407f2c70'	System	07 Aug 2020 19:12:24
User entered 'None (1)'	System	07 Aug 2020 19:12:24

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:24:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-07T15:12:22', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '8aec9276-186a-4e61-9ceb-262f407f2c70'	System	07 Aug 2020 19:12:24
User entered '07 Aug 2020 15:12'	System	07 Aug 2020 19:12:24

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:24:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:00'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:24:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 14:09:34
User entered 'Day 4'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:24:53

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 (b99ae654c582cef3)', Time: '2020-08-08T16:14:07', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'a9007510-a070-416e-b266-b3cbc0645d91'	System	08 Aug 2020 20:14:35
User entered 'None (1)'	System	08 Aug 2020 20:14:35

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:24:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-08T16:14:10', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'a9007510-a070-416e-b266-b3cbc0645d91'	System	08 Aug 2020 20:14:35
User entered 'No (N)'	System	08 Aug 2020 20:14:35

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-08T16:14:12', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'a9007510-a070-416e-b266-b3cbc0645d91'	System	08 Aug 2020 20:14:35
User entered 'No (N)'	System	08 Aug 2020 20:14:35

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:24:53

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 (b99ae654c582cef3)', Time: '2020-08-08T16:14:24', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'a9007510-a070-416e-b266-b3cbc0645d91'	System	08 Aug 2020 20:14:35
User entered 'None (1)'	System	08 Aug 2020 20:14:35

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:24:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-08T16:14:30', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'a9007510-a070-416e-b266-b3cbc0645d91'	System	08 Aug 2020 20:14:35
User entered '08 Aug 2020 16:14'	System	08 Aug 2020 20:14:35

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:24:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:24:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 14:09:34
User entered 'Day 5'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:24:53

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 (b99ae654c582cef3)', Time: '2020-08-09T17:00:24', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'c6f7acd4-96a7-4cdf-b477-ae77c9ad26f7'	System	09 Aug 2020 21:01:10
User entered 'None (1)'	System	09 Aug 2020 21:01:10

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:24:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-09T17:00:27', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'c6f7acd4-96a7-4cdf-b477-ae77c9ad26f7'	System	09 Aug 2020 21:01:10
User entered 'No (N)'	System	09 Aug 2020 21:01:10

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-09T17:00:37', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'c6f7acd4-96a7-4cdf-b477-ae77c9ad26f7'	System	09 Aug 2020 21:01:10
User entered 'No (N)'	System	09 Aug 2020 21:01:10

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:24:53

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 (b99ae654c582cef3)', Time: '2020-08-09T17:00:56', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'c6f7acd4-96a7-4cdf-b477-ae77c9ad26f7'	System	09 Aug 2020 21:01:10
User entered 'None (1)'	System	09 Aug 2020 21:01:10

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:24:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-09T17:01:04', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'c6f7acd4-96a7-4cdf-b477-ae77c9ad26f7'	System	09 Aug 2020 21:01:10
User entered '09 Aug 2020 17:01'	System	09 Aug 2020 21:01:10

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:24:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:24:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 14:09:34
User entered 'Day 6'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:24:53

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 (b99ae654c582cef3)', Time: '2020-08-10T16:12:12', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'd4567b39-1425-4966-b0d0-5657a73d506f'	System	10 Aug 2020 20:12:37
User entered 'None (1)'	System	10 Aug 2020 20:12:37

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:24:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-10T16:12:15', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'd4567b39-1425-4966-b0d0-5657a73d506f'	System	10 Aug 2020 20:12:37
User entered 'No (N)'	System	10 Aug 2020 20:12:37

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-10T16:12:24', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'd4567b39-1425-4966-b0d0-5657a73d506f'	System	10 Aug 2020 20:12:37
User entered 'No (N)'	System	10 Aug 2020 20:12:37

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:24:53

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 (b99ae654c582cef3)', Time: '2020-08-10T16:12:26', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'd4567b39-1425-4966-b0d0-5657a73d506f'	System	10 Aug 2020 20:12:37
User entered 'None (1)'	System	10 Aug 2020 20:12:37

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:24:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-10T16:12:35', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'd4567b39-1425-4966-b0d0-5657a73d506f'	System	10 Aug 2020 20:12:37
User entered '10 Aug 2020 16:12'	System	10 Aug 2020 20:12:37

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:24:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:24:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 14:09:34
User entered 'Day 7'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:24:53

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 (b99ae654c582cef3)', Time: '2020-08-11T17:53:21', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'af58ddf5-64da-4c62-aa54-fcf6b721b3b4'	System	11 Aug 2020 21:53:42
User entered 'None (1)'	System	11 Aug 2020 21:53:42

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:24:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-11T17:53:24', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'af58ddf5-64da-4c62-aa54-fcf6b721b3b4'	System	11 Aug 2020 21:53:42
User entered 'No (N)'	System	11 Aug 2020 21:53:42

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-11T17:53:26', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'af58ddf5-64da-4c62-aa54-fcf6b721b3b4'	System	11 Aug 2020 21:53:42
User entered 'No (N)'	System	11 Aug 2020 21:53:42

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:24:53

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 (b99ae654c582cef3)', Time: '2020-08-11T17:53:32', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'af58ddf5-64da-4c62-aa54-fcf6b721b3b4'	System	11 Aug 2020 21:53:42
User entered 'None (1)'	System	11 Aug 2020 21:53:42

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:24:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-11T17:53:40', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'af58ddf5-64da-4c62-aa54-fcf6b721b3b4'	System	11 Aug 2020 21:53:42
User entered '11 Aug 2020 17:53'	System	11 Aug 2020 21:53:42

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:24:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:24:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 14:09:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-05T10:32:34', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '5e55c64f-1b73-4718-a7e4-118b51f39c5b'	System	05 Aug 2020 14:33:15
User entered 'None (0)'	System	05 Aug 2020 14:33:15

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-05T10:32:38', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '5e55c64f-1b73-4718-a7e4-118b51f39c5b'	System	05 Aug 2020 14:33:15
User entered 'None (0)'	System	05 Aug 2020 14:33:15

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-05T10:32:43', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '5e55c64f-1b73-4718-a7e4-118b51f39c5b'	System	05 Aug 2020 14:33:15
User entered 'None (0)'	System	05 Aug 2020 14:33:15

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-05T10:32:46', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '5e55c64f-1b73-4718-a7e4-118b51f39c5b'	System	05 Aug 2020 14:33:15
User entered 'None (0)'	System	05 Aug 2020 14:33:15

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-05T10:32:49', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '5e55c64f-1b73-4718-a7e4-118b51f39c5b'	System	05 Aug 2020 14:33:15
User entered 'None (0)'	System	05 Aug 2020 14:33:15

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-05T10:32:52', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '5e55c64f-1b73-4718-a7e4-118b51f39c5b'	System	05 Aug 2020 14:33:15
User entered 'None (0)'	System	05 Aug 2020 14:33:15

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

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 (b99ae654c582cef3)', Time: '2020-08-05T10:33:03', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '5e55c64f-1b73-4718-a7e4-118b51f39c5b'	System	05 Aug 2020 14:33:15
User entered 'No (N)'	System	05 Aug 2020 14:33:15

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-05T10:33:12', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '5e55c64f-1b73-4718-a7e4-118b51f39c5b'	System	05 Aug 2020 14:33:15
User entered '05 Aug 2020 10:33'	System	05 Aug 2020 14:33:15

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 10:19'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 12:49'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 14:09:34
User entered 'Day 1, after vaccination (at home)'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-05T16:59:36', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'da44ce19-c05a-44a3-af38-04a1aaacac8e'	System	05 Aug 2020 21:00:11
User entered 'None (0)'	System	05 Aug 2020 21:00:11

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-05T16:59:39', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'da44ce19-c05a-44a3-af38-04a1aaacac8e'	System	05 Aug 2020 21:00:11
User entered 'None (0)'	System	05 Aug 2020 21:00:11

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-05T16:59:42', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'da44ce19-c05a-44a3-af38-04a1aaacac8e'	System	05 Aug 2020 21:00:11
User entered 'None (0)'	System	05 Aug 2020 21:00:11

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-05T16:59:46', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'da44ce19-c05a-44a3-af38-04a1aaacac8e'	System	05 Aug 2020 21:00:11
User entered 'None (0)'	System	05 Aug 2020 21:00:11

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-05T16:59:55', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'da44ce19-c05a-44a3-af38-04a1aaacac8e'	System	05 Aug 2020 21:00:11
User entered 'None (0)'	System	05 Aug 2020 21:00:11

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-05T16:59:58', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'da44ce19-c05a-44a3-af38-04a1aaacac8e'	System	05 Aug 2020 21:00:11
User entered 'None (0)'	System	05 Aug 2020 21:00:11

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

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 (b99ae654c582cef3)', Time: '2020-08-05T17:00:03', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'da44ce19-c05a-44a3-af38-04a1aaacac8e'	System	05 Aug 2020 21:00:11
User entered 'No (N)'	System	05 Aug 2020 21:00:11

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-05T17:00:08', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'da44ce19-c05a-44a3-af38-04a1aaacac8e'	System	05 Aug 2020 21:00:11
User entered '05 Aug 2020 17:00'	System	05 Aug 2020 21:00:11

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Aug 2020 13:44'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 11:59'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 14:09:34
User entered 'Day 2'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:24:53

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-06T17:00:28', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'f9103ad0-e241-428c-b8e1-4b8753c95144'	System	06 Aug 2020 21:01:24
User entered 'No interference with activity (1)'	System	06 Aug 2020 21:01:24

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:24:53

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-06T17:00:46', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'f9103ad0-e241-428c-b8e1-4b8753c95144'	System	06 Aug 2020 21:01:24
User entered 'None (0)'	System	06 Aug 2020 21:01:24

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:24:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-06T17:00:51', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'f9103ad0-e241-428c-b8e1-4b8753c95144'	System	06 Aug 2020 21:01:24
User entered 'None (0)'	System	06 Aug 2020 21:01:24

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:24:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-06T17:00:54', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'f9103ad0-e241-428c-b8e1-4b8753c95144'	System	06 Aug 2020 21:01:24
User entered 'None (0)'	System	06 Aug 2020 21:01:24

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:24:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-06T17:01:01', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'f9103ad0-e241-428c-b8e1-4b8753c95144'	System	06 Aug 2020 21:01:24
User entered 'None (0)'	System	06 Aug 2020 21:01:24

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:24:53

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-06T17:01:05', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'f9103ad0-e241-428c-b8e1-4b8753c95144'	System	06 Aug 2020 21:01:24
User entered 'None (0)'	System	06 Aug 2020 21:01:24

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:24:53

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 (b99ae654c582cef3)', Time: '2020-08-06T17:01:09', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'f9103ad0-e241-428c-b8e1-4b8753c95144'	System	06 Aug 2020 21:01:24
User entered 'No (N)'	System	06 Aug 2020 21:01:24

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:24:53

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-06T17:01:20', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'f9103ad0-e241-428c-b8e1-4b8753c95144'	System	06 Aug 2020 21:01:24
User entered '06 Aug 2020 17:01'	System	06 Aug 2020 21:01:24

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:24:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Aug 2020 12:00'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:24:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 11:59'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 14:09:34
User entered 'Day 3'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:24:53

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-07T15:12:28', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'b2f7a04c-c33a-417d-82a0-04453280bfc8'	System	07 Aug 2020 19:13:07
User entered 'None (0)'	System	07 Aug 2020 19:13:07

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:24:53

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-07T15:12:33', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'b2f7a04c-c33a-417d-82a0-04453280bfc8'	System	07 Aug 2020 19:13:07
User entered 'None (0)'	System	07 Aug 2020 19:13:07

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:24:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-07T15:12:36', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'b2f7a04c-c33a-417d-82a0-04453280bfc8'	System	07 Aug 2020 19:13:07
User entered 'None (0)'	System	07 Aug 2020 19:13:07

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:24:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-07T15:12:39', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'b2f7a04c-c33a-417d-82a0-04453280bfc8'	System	07 Aug 2020 19:13:07
User entered 'None (0)'	System	07 Aug 2020 19:13:07

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:24:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-07T15:12:42', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'b2f7a04c-c33a-417d-82a0-04453280bfc8'	System	07 Aug 2020 19:13:07
User entered 'None (0)'	System	07 Aug 2020 19:13:07

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:24:53

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-07T15:12:47', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'b2f7a04c-c33a-417d-82a0-04453280bfc8'	System	07 Aug 2020 19:13:07
User entered 'None (0)'	System	07 Aug 2020 19:13:07

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:24:53

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 (b99ae654c582cef3)', Time: '2020-08-07T15:12:56', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'b2f7a04c-c33a-417d-82a0-04453280bfc8'	System	07 Aug 2020 19:13:07
User entered 'No (N)'	System	07 Aug 2020 19:13:07

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:24:53

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-07T15:13:05', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'b2f7a04c-c33a-417d-82a0-04453280bfc8'	System	07 Aug 2020 19:13:07
User entered '07 Aug 2020 15:13'	System	07 Aug 2020 19:13:07

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:24:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Aug 2020 12:00'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:24:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 11:59'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 14:09:34
User entered 'Day 4'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:24:53

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-08T16:14:43', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '8df1fe2e-d4d1-4c1e-8c4c-0bc7650d7b2a'	System	08 Aug 2020 20:15:49
User entered 'None (0)'	System	08 Aug 2020 20:15:49

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:24:53

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-08T16:15:20', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '8df1fe2e-d4d1-4c1e-8c4c-0bc7650d7b2a'	System	08 Aug 2020 20:15:49
User entered 'None (0)'	System	08 Aug 2020 20:15:49

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:24:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-08T16:15:22', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '8df1fe2e-d4d1-4c1e-8c4c-0bc7650d7b2a'	System	08 Aug 2020 20:15:49
User entered 'None (0)'	System	08 Aug 2020 20:15:49

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:24:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-08T16:15:27', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '8df1fe2e-d4d1-4c1e-8c4c-0bc7650d7b2a'	System	08 Aug 2020 20:15:49
User entered 'None (0)'	System	08 Aug 2020 20:15:49

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:24:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-08T16:15:30', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '8df1fe2e-d4d1-4c1e-8c4c-0bc7650d7b2a'	System	08 Aug 2020 20:15:49
User entered 'None (0)'	System	08 Aug 2020 20:15:49

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:24:53

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-08T16:15:33', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '8df1fe2e-d4d1-4c1e-8c4c-0bc7650d7b2a'	System	08 Aug 2020 20:15:49
User entered 'None (0)'	System	08 Aug 2020 20:15:49

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:24:53

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 (b99ae654c582cef3)', Time: '2020-08-08T16:15:40', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '8df1fe2e-d4d1-4c1e-8c4c-0bc7650d7b2a'	System	08 Aug 2020 20:15:49
User entered 'No (N)'	System	08 Aug 2020 20:15:49

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:24:53

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-08T16:15:46', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '8df1fe2e-d4d1-4c1e-8c4c-0bc7650d7b2a'	System	08 Aug 2020 20:15:49
User entered '08 Aug 2020 16:15'	System	08 Aug 2020 20:15:49

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:24:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Aug 2020 12:00'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:24:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 11:59'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 14:09:34
User entered 'Day 5'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:24:53

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-09T17:01:10', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'b3b4d709-d2b2-4c89-9969-f7ef5df530b3'	System	09 Aug 2020 21:01:37
User entered 'None (0)'	System	09 Aug 2020 21:01:37

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:24:53

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-09T17:01:13', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'b3b4d709-d2b2-4c89-9969-f7ef5df530b3'	System	09 Aug 2020 21:01:37
User entered 'None (0)'	System	09 Aug 2020 21:01:37

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:24:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-09T17:01:15', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'b3b4d709-d2b2-4c89-9969-f7ef5df530b3'	System	09 Aug 2020 21:01:37
User entered 'None (0)'	System	09 Aug 2020 21:01:37

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:24:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-09T17:01:18', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'b3b4d709-d2b2-4c89-9969-f7ef5df530b3'	System	09 Aug 2020 21:01:37
User entered 'None (0)'	System	09 Aug 2020 21:01:37

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:24:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-09T17:01:20', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'b3b4d709-d2b2-4c89-9969-f7ef5df530b3'	System	09 Aug 2020 21:01:37
User entered 'None (0)'	System	09 Aug 2020 21:01:37

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:24:53

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-09T17:01:24', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'b3b4d709-d2b2-4c89-9969-f7ef5df530b3'	System	09 Aug 2020 21:01:37
User entered 'None (0)'	System	09 Aug 2020 21:01:37

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:24:53

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 (b99ae654c582cef3)', Time: '2020-08-09T17:01:26', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'b3b4d709-d2b2-4c89-9969-f7ef5df530b3'	System	09 Aug 2020 21:01:37
User entered 'No (N)'	System	09 Aug 2020 21:01:37

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:24:53

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-09T17:01:32', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'b3b4d709-d2b2-4c89-9969-f7ef5df530b3'	System	09 Aug 2020 21:01:37
User entered '09 Aug 2020 17:01'	System	09 Aug 2020 21:01:37

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:24:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Aug 2020 12:00'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:24:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 11:59'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 14:09:34
User entered 'Day 6'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:24:53

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-10T16:12:41', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '3a3bb54a-5c6b-4418-b6cb-0beab3e4256b'	System	10 Aug 2020 20:13:19
User entered 'None (0)'	System	10 Aug 2020 20:13:19

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:24:53

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-10T16:12:44', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '3a3bb54a-5c6b-4418-b6cb-0beab3e4256b'	System	10 Aug 2020 20:13:19
User entered 'None (0)'	System	10 Aug 2020 20:13:19

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:24:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-10T16:12:47', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '3a3bb54a-5c6b-4418-b6cb-0beab3e4256b'	System	10 Aug 2020 20:13:19
User entered 'None (0)'	System	10 Aug 2020 20:13:19

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:24:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-10T16:12:59', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '3a3bb54a-5c6b-4418-b6cb-0beab3e4256b'	System	10 Aug 2020 20:13:19
User entered 'None (0)'	System	10 Aug 2020 20:13:19

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:24:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-10T16:13:03', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '3a3bb54a-5c6b-4418-b6cb-0beab3e4256b'	System	10 Aug 2020 20:13:19
User entered 'None (0)'	System	10 Aug 2020 20:13:19

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:24:53

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-10T16:13:08', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '3a3bb54a-5c6b-4418-b6cb-0beab3e4256b'	System	10 Aug 2020 20:13:19
User entered 'None (0)'	System	10 Aug 2020 20:13:19

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:24:53

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 (b99ae654c582cef3)', Time: '2020-08-10T16:13:12', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '3a3bb54a-5c6b-4418-b6cb-0beab3e4256b'	System	10 Aug 2020 20:13:19
User entered 'No (N)'	System	10 Aug 2020 20:13:19

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:24:53

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-10T16:13:17', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '3a3bb54a-5c6b-4418-b6cb-0beab3e4256b'	System	10 Aug 2020 20:13:19
User entered '10 Aug 2020 16:13'	System	10 Aug 2020 20:13:19

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:24:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 12:00'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:24:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 11:59'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 14:09:34
User entered 'Day 7'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:24:53

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-11T17:53:48', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'a3ac5ab2-26d9-4320-86e6-17eff3424563'	System	11 Aug 2020 21:54:19
User entered 'None (0)'	System	11 Aug 2020 21:54:19

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:24:53

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-11T17:53:51', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'a3ac5ab2-26d9-4320-86e6-17eff3424563'	System	11 Aug 2020 21:54:19
User entered 'None (0)'	System	11 Aug 2020 21:54:19

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:24:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-11T17:53:53', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'a3ac5ab2-26d9-4320-86e6-17eff3424563'	System	11 Aug 2020 21:54:19
User entered 'None (0)'	System	11 Aug 2020 21:54:19

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:24:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-11T17:53:58', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'a3ac5ab2-26d9-4320-86e6-17eff3424563'	System	11 Aug 2020 21:54:19
User entered 'None (0)'	System	11 Aug 2020 21:54:19

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:24:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-11T17:54:02', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'a3ac5ab2-26d9-4320-86e6-17eff3424563'	System	11 Aug 2020 21:54:19
User entered 'None (0)'	System	11 Aug 2020 21:54:19

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:24:53

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-11T17:54:07', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'a3ac5ab2-26d9-4320-86e6-17eff3424563'	System	11 Aug 2020 21:54:19
User entered 'None (0)'	System	11 Aug 2020 21:54:19

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:24:53

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 (b99ae654c582cef3)', Time: '2020-08-11T17:54:11', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'a3ac5ab2-26d9-4320-86e6-17eff3424563'	System	11 Aug 2020 21:54:19
User entered 'No (N)'	System	11 Aug 2020 21:54:19

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:24:53

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-08-11T17:54:15', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'a3ac5ab2-26d9-4320-86e6-17eff3424563'	System	11 Aug 2020 21:54:19
User entered '11 Aug 2020 17:54'	System	11 Aug 2020 21:54:19

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:24:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 12:00'	System	05 Aug 2020 14:09:34

US3432016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:24:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	05 Aug 2020 14:09:34

US3432016

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:25:04
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	12 Aug 2020 18:06:25
	(b) (4)	

US3432016

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:25:04
User entered '12 Aug 2020'	Xhoi Mitre (b) (4)	12 Aug 2020 18:06:25
	(b) (4)	

US3432016

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:25:04
User entered 'Contact Made (CONTACT MADE)'	Xhoi Mitre (b) (4) (b) (4)	12 Aug 2020 18:06:25

US3432016

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:25:04
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	12 Aug 2020 18:06:25

US3432016

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:25:09
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) (b) (4)	12 Aug 2020 18:06:38

US3432016

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:53

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 18:06:38

US3432016

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:25:31
User entered 'Yes (Y)'	Phoebe Cunningham	19 Aug 2020 18:57:39
	(b) (4)	

US3432016

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:25:31
User entered '19 Aug 2020'	Phoebe Cunningham (b) (4)	19 Aug 2020 18:57:39

US3432016

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:25:31
User entered 'Contact Made (CONTACT MADE)'	Phoebe Cunningham (b) (4)	19 Aug 2020 18:57:39

US3432016

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:25:31
User entered empty.	Phoebe Cunningham (b) (4)	19 Aug 2020 18:57:39

US3432016

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:25:37
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	19 Aug 2020 18:57:47

US3432016

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:53

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 18:57:47

US3432016

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:25:42
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	26 Aug 2020 20:03:08

US3432016

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:25:42
User entered '26 Aug 2020'	Phoebe Cunningham (b) (4)	26 Aug 2020 20:03:08

US3432016

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:25:42
User entered 'Contact Made (CONTACT MADE)'	Phoebe Cunningham (b) (4)	26 Aug 2020 20:03:08

US3432016

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:25:42
User entered empty.	Phoebe Cunningham (b) (4)	26 Aug 2020 20:03:08

US3432016

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:25:45
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	26 Aug 2020 20:03:12

US3432016

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:53

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 20:03:12

US3432016

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:24:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:59:35
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 14:20:24

US3432016

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:59:35
User entered '02 Sep 2020'	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 14:20:24

US3432016

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:59:35
User entered 'Clinic (Clinic)'	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 14:20:24

US3432016

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:24:53

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	02 Sep 2020 14:20:24

US3432016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:53

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 14:23:13

US3432016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:01:08
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 14:23:13

US3432016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:01:08
User entered '02 Sep 2020'	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 14:23:13

US3432016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:01:08
User entered '08:46'	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 14:23:13

(

US3432016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered '02 Sep 2020 08:46'	System	02 Sep 2020 14:23:13

US3432016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:53

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:01:08
User entered '36.7' C	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 14:23:13

US3432016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:53

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:01:08
User entered 'Oral (Oral)'	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 14:23:13

US3432016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:53

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:01:08
User entered empty.	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 14:23:13

US3432016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:01:08
User entered '88'	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 14:23:13

US3432016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:53

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	02 Sep 2020 14:23:13

US3432016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:01:08
User entered '14'	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 14:23:13

US3432016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	02 Sep 2020 14:23:13

US3432016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:01:08
User entered '124'	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 14:23:13

US3432016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Sep 2020 14:23:13

US3432016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:53

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:01:08
User entered '68'	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 14:23:13

US3432016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:24:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Sep 2020 14:23:13

US3432016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:53

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 14:23:13

US3432016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:01:08
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 19:22:14
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 19:22:14
User entered 'Yes (Y)' reason for change: Data Entry Error	Jun Bai Park Chang	11 Sep 2020 19:22:14
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Sep 2020 14:23:13
User entered empty.	Julia Klopfer (b) (4)	02 Sep 2020 14:23:13

US3432016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:01:08
User entered '2 Sep 2020' reason for change: Data Entry Error	Jun Bai Park Chang	11 Sep 2020 19:22:14
User entered empty.	(b) (4)	
	Julia Klopfer (b) (4)	02 Sep 2020 14:23:13
	(b) (4)	

US3432016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:01:08
User entered '10:43' reason for change: Data Entry Error	Jun Bai Park Chang	11 Sep 2020 19:22:14
User entered empty.	(b) (4)	
	Julia Klopfer (b) (4)	02 Sep 2020 14:23:13
	(b) (4)	

US3432016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered '2 Sep 2020 10:43'	System	11 Sep 2020 19:22:14
User entered empty.	System	02 Sep 2020 14:23:13

US3432016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:53

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:01:08
User entered '98.4' F reason for change: Data Entry Error	Jun Bai Park Chang (b) (4)	11 Sep 2020 19:22:14
User entered empty.	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 14:23:13

US3432016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:53

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:01:08
User entered 'Oral (Oral)' reason for change: Data Entry Error	Jun Bai Park Chang	11 Sep 2020 19:22:14
User entered empty.	(b) (4)	
	Julia Klopfer (b) (4)	02 Sep 2020 14:23:13
	(b) (4)	

US3432016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:53

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:01:08
User entered empty.	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 14:23:13

US3432016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:01:08
User entered '72' reason for change: Data Entry Error	Jun Bai Park Chang (b) (4)	11 Sep 2020 19:22:14
User entered empty.	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 14:23:13

US3432016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:53

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Sep 2020 19:22:14
User entered empty.	System	02 Sep 2020 14:23:13

US3432016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:01:08
User entered '15' reason for change: Data Entry Error	Jun Bai Park Chang (b) (4)	11 Sep 2020 19:22:14
User entered empty.	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 14:23:13

US3432016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	11 Sep 2020 19:22:14
User entered empty.	System	02 Sep 2020 14:23:13

US3432016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:53

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:01:08
User entered '127' reason for change: Data Entry Error	Jun Bai Park Chang (b) (4)	11 Sep 2020 19:22:14
User entered empty.	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 14:23:13

US3432016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Sep 2020 19:22:14
User entered empty.	System	02 Sep 2020 14:23:13

US3432016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:53

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:01:08
User entered '76' reason for change: Data Entry Error	Jun Bai Park Chang (b) (4)	11 Sep 2020 19:22:14
User entered empty.	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 14:23:13

US3432016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:24:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Sep 2020 19:22:14
User entered empty.	System	02 Sep 2020 14:23:13

US3432016

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:24:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:02:09
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 14:23:29

US3432016

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:24:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:02:09
User entered '02 Sep 2020'	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 14:23:29

US3432016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:24:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:02:26
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 14:20:48

US3432016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:24:53

[If No, reason not given](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:02:26
User entered empty.	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 14:20:48

US3432016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:02:26
User entered empty.	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 14:20:48

US3432016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:24:53

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	02 Sep 2020 14:20:48

US3432016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:24:53

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:02:26
User entered '02 Sep 2020'	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 14:20:48

US3432016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:24:53

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:02:26
User entered '10:13'	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 14:20:48

US3432016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:24:53

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 10:13'	System	02 Sep 2020 14:20:48

US3432016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:24:53

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:02:26
User entered 'Left Arm (LEFT ARM)'	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 14:20:48

US3432016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:24:53

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:02:26
User entered 'ONCE'	System	02 Sep 2020 14:20:48

US3432016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:24:53

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	02 Sep 2020 14:20:48

US3432016

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:24:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:02:39
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 22:16:48

US3432016

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:24:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:02:39
User entered '02 Sep 2020'	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 22:16:48

US3432016

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:24:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Per source the time is 09:35' (Site from CRA).	(b) (4), (b) (6)	06 Oct 2020 16:56:53
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:56:40
Query 'Per source the time is 09:35' answered with 'updated' (Site from CRA).	Monica Feeley (b) (4)	05 Oct 2020 16:41:48
User entered '09:35' reason for change: Data Entry Error	Monica Feeley (b) (4)	05 Oct 2020 16:41:44
User opened query 'Per source the time is 09:35' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 19:03:40
DataPoint Un-verified.	(b) (4), (b) (6)	23 Sep 2020 19:02:43
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:02:39
User entered '09:09'	Julia Klopfer (b) (4)	02 Sep 2020 22:16:48

US3432016

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:24:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 09:35'	System	05 Oct 2020 16:41:44
User entered '02 Sep 2020 09:09'	System	02 Sep 2020 22:16:48

US3432016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:24:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:03:48
User entered '02 Sep 2020'	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 22:21:18

US3432016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:24:53

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 22:21:18

US3432016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:24:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:03:48
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 22:21:18

US3432016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:24:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:03:48
User entered '09:22'	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 22:21:18

US3432016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:24:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 09:22'	System	02 Sep 2020 22:21:18

US3432016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:24:53

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 22:21:18

US3432016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:24:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:03:48
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 22:21:18

US3432016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:24:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:03:48
User entered empty.	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 22:21:18

US3432016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:24:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 22:21:18

US3432016

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:05:25
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 22:21:23

US3432016

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:53

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 22:21:23

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 14:20:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-02T10:50:06', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '4ff6a14c-ecb5-4e13-9d12-a0c49e93b2ff'	System	02 Sep 2020 14:50:28
User entered 'Yes (Y)'	System	02 Sep 2020 14:50:28

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-02T10:50:12', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '4ff6a14c-ecb5-4e13-9d12-a0c49e93b2ff'	System	02 Sep 2020 14:50:28
User entered '98.4'	System	02 Sep 2020 14:50:28

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-02T10:50:16', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '4ff6a14c-ecb5-4e13-9d12-a0c49e93b2ff'	System	02 Sep 2020 14:50:28
User entered 'No (N)'	System	02 Sep 2020 14:50:28

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-02T10:50:26', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '4ff6a14c-ecb5-4e13-9d12-a0c49e93b2ff'	System	02 Sep 2020 14:50:28
User entered '02 Sep 2020 10:50'	System	02 Sep 2020 14:50:28

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 10:33'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 13:03'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 14:20:48
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-02T15:38:59', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '09e161b4-8f2e-48c7-a431-f956806b4c40'	System	02 Sep 2020 19:39:14
User entered 'Yes (Y)'	System	02 Sep 2020 19:39:14

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-02T15:39:05', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '09e161b4-8f2e-48c7-a431-f956806b4c40'	System	02 Sep 2020 19:39:14
User entered '98.2'	System	02 Sep 2020 19:39:14

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-02T15:39:08', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '09e161b4-8f2e-48c7-a431-f956806b4c40'	System	02 Sep 2020 19:39:14
User entered 'No (N)'	System	02 Sep 2020 19:39:14

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-02T15:39:13', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '09e161b4-8f2e-48c7-a431-f956806b4c40'	System	02 Sep 2020 19:39:14
User entered '02 Sep 2020 15:39'	System	02 Sep 2020 19:39:14

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 13:58'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 14:20:48
User entered 'Day 2'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:24:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-03T15:51:28', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'b9b9bcd0-d0e9-4220-a43e-5ffc5690d055'	System	03 Sep 2020 19:52:03
User entered 'Yes (Y)'	System	03 Sep 2020 19:52:03

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:24:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-03T15:51:34', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'b9b9bcd0-d0e9-4220-a43e-5ffc5690d055'	System	03 Sep 2020 19:52:03
User entered '100.7'	System	03 Sep 2020 19:52:03

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-03T15:51:49', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'b9b9bcd0-d0e9-4220-a43e-5ffc5690d055'	System	03 Sep 2020 19:52:03
User entered 'No (N)'	System	03 Sep 2020 19:52:03

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:24:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-03T15:52:00', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'b9b9bcd0-d0e9-4220-a43e-5ffc5690d055'	System	03 Sep 2020 19:52:03
User entered '03 Sep 2020 15:52'	System	03 Sep 2020 19:52:03

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:24:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:24:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 14:20:48
User entered 'Day 3'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:24:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-04T16:18:44', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'a23941e9-9c2e-40eb-baba-ffb15956d58f'	System	04 Sep 2020 20:19:05
User entered 'Yes (Y)'	System	04 Sep 2020 20:19:05

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:24:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-04T16:18:50', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'a23941e9-9c2e-40eb-baba-ffb15956d58f'	System	04 Sep 2020 20:19:05
User entered '98.2'	System	04 Sep 2020 20:19:05

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-04T16:18:57', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'a23941e9-9c2e-40eb-baba-ffb15956d58f'	System	04 Sep 2020 20:19:05
User entered 'No (N)'	System	04 Sep 2020 20:19:05

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:24:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-04T16:19:03', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'a23941e9-9c2e-40eb-baba-ffb15956d58f'	System	04 Sep 2020 20:19:05
User entered '04 Sep 2020 16:19'	System	04 Sep 2020 20:19:05

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:24:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:24:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 14:20:48
User entered 'Day 4'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:24:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-05T15:59:11', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'c628a462-294b-4f58-b972-d6fa6f68f987'	System	05 Sep 2020 19:59:32
User entered 'Yes (Y)'	System	05 Sep 2020 19:59:32

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:24:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-05T15:59:17', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'c628a462-294b-4f58-b972-d6fa6f68f987'	System	05 Sep 2020 19:59:32
User entered '98.4'	System	05 Sep 2020 19:59:32

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-05T15:59:22', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'c628a462-294b-4f58-b972-d6fa6f68f987'	System	05 Sep 2020 19:59:32
User entered 'No (N)'	System	05 Sep 2020 19:59:32

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:24:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-05T15:59:27', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'c628a462-294b-4f58-b972-d6fa6f68f987'	System	05 Sep 2020 19:59:32
User entered '05 Sep 2020 15:59'	System	05 Sep 2020 19:59:32

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:24:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:24:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 14:20:48
User entered 'Day 5'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:24:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-06T17:31:01', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '21bcce7b-9779-44fa-ac82-ce7f915d3d35'	System	06 Sep 2020 21:31:26
User entered 'Yes (Y)'	System	06 Sep 2020 21:31:26

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:24:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-06T17:31:16', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '21bcce7b-9779-44fa-ac82-ce7f915d3d35'	System	06 Sep 2020 21:31:26
User entered '98.3'	System	06 Sep 2020 21:31:26

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-06T17:31:21', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '21bcce7b-9779-44fa-ac82-ce7f915d3d35'	System	06 Sep 2020 21:31:26
User entered 'No (N)'	System	06 Sep 2020 21:31:26

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:24:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-06T17:31:24', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '21bcce7b-9779-44fa-ac82-ce7f915d3d35'	System	06 Sep 2020 21:31:26
User entered '06 Sep 2020 17:31'	System	06 Sep 2020 21:31:26

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:24:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:24:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 14:20:48
User entered 'Day 6'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:24:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-07T15:42:38', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '6b66f553-e2a3-43d0-81eb-e88bb54faad6'	System	07 Sep 2020 19:43:37
User entered 'Yes (Y)'	System	07 Sep 2020 19:43:37

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:24:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-07T15:42:45', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '6b66f553-e2a3-43d0-81eb-e88bb54faad6'	System	07 Sep 2020 19:43:37
User entered '98.4'	System	07 Sep 2020 19:43:37

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-07T15:43:12', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '6b66f553-e2a3-43d0-81eb-e88bb54faad6'	System	07 Sep 2020 19:43:37
User entered 'Yes (Y)'	System	07 Sep 2020 19:43:37

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	15 Sep 2020 09:42:41
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Will record this at the next safety call.' (Site from System).	Jun Bai Park Chang (b) (4)	14 Sep 2020 14:41:19
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	07 Sep 2020 19:43:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-07T15:43:24', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '6b66f553-e2a3-43d0-81eb-e88bb54faad6'	System	07 Sep 2020 19:43:37
User entered '1'	System	07 Sep 2020 19:43:37

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:24:53

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Will record this at the next safety call.' (Site from System).	(b) (4), (b) (6)	15 Sep 2020 09:42:38
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-07T15:43:24', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '6b66f553-e2a3-43d0-81eb-e88bb54faad6'	Jun Bai Park Chang (b) (4)	14 Sep 2020 14:41:24
User entered '1'	System	07 Sep 2020 19:43:37

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:24:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-07T15:43:33', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '6b66f553-e2a3-43d0-81eb-e88bb54faad6'	System	07 Sep 2020 19:43:37
User entered '07 Sep 2020 15:43'	System	07 Sep 2020 19:43:37

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:24:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:24:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 14:20:48
User entered 'Day 7'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:24:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-08T15:53:32', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'eae7e62-eb3d-4a80-b138-0badf7b72c44'	System	08 Sep 2020 19:53:51
User entered 'Yes (Y)'	System	08 Sep 2020 19:53:51

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:24:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-08T15:53:38', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'eae7e62-eb3d-4a80-b138-0badf7b72c44'	System	08 Sep 2020 19:53:51
User entered '98.3'	System	08 Sep 2020 19:53:51

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-08T15:53:41', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'eae7e62-eb3d-4a80-b138-0badf7b72c44'	System	08 Sep 2020 19:53:51
User entered 'No (N)'	System	08 Sep 2020 19:53:51

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:24:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-08T15:53:45', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'eae7e62-eb3d-4a80-b138-0badf7b72c44'	System	08 Sep 2020 19:53:51
User entered '08 Sep 2020 15:53'	System	08 Sep 2020 19:53:51

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:24:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:24:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 14:20:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

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 (b99ae654c582cef3)', Time: '2020-09-02T10:50:36', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '7e1f7f48-e9ae-49b7-ab72-916057dc41d3'	System	02 Sep 2020 14:51:02
User entered 'None (1)'	System	02 Sep 2020 14:51:02

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-02T10:50:43', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '7e1f7f48-e9ae-49b7-ab72-916057dc41d3'	System	02 Sep 2020 14:51:02
User entered 'No (N)'	System	02 Sep 2020 14:51:02

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-02T10:50:46', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '7e1f7f48-e9ae-49b7-ab72-916057dc41d3'	System	02 Sep 2020 14:51:02
User entered 'No (N)'	System	02 Sep 2020 14:51:02

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

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 (b99ae654c582cef3)', Time: '2020-09-02T10:50:53', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '7e1f7f48-e9ae-49b7-ab72-916057dc41d3'	System	02 Sep 2020 14:51:02
User entered 'None (1)'	System	02 Sep 2020 14:51:02

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-02T10:50:59', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '7e1f7f48-e9ae-49b7-ab72-916057dc41d3'	System	02 Sep 2020 14:51:02
User entered '02 Sep 2020 10:50'	System	02 Sep 2020 14:51:02

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 10:33'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 13:03'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 14:20:48
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

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 (b99ae654c582cef3)', Time: '2020-09-02T15:39:28', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '19098299-2ff5-40b7-93b9-f21ecf0c997f'	System	02 Sep 2020 19:40:14
User entered 'None (1)'	System	02 Sep 2020 19:40:14

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-02T15:39:48', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '19098299-2ff5-40b7-93b9-f21ecf0c997f'	System	02 Sep 2020 19:40:14
User entered 'No (N)'	System	02 Sep 2020 19:40:14

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-02T15:39:56', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '19098299-2ff5-40b7-93b9-f21ecf0c997f'	System	02 Sep 2020 19:40:14
User entered 'No (N)'	System	02 Sep 2020 19:40:14

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

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 (b99ae654c582cef3)', Time: '2020-09-02T15:40:02', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '19098299-2ff5-40b7-93b9-f21ecf0c997f'	System	02 Sep 2020 19:40:14
User entered 'None (1)'	System	02 Sep 2020 19:40:14

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-02T15:40:09', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '19098299-2ff5-40b7-93b9-f21ecf0c997f'	System	02 Sep 2020 19:40:14
User entered '02 Sep 2020 15:40'	System	02 Sep 2020 19:40:14

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 13:58'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 14:20:48
User entered 'Day 2'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:24:53

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 (b99ae654c582cef3)', Time: '2020-09-03T15:52:27', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'ef44d726-e452-4cb5-ab55-82089ef0e264'	System	03 Sep 2020 19:52:52
User entered 'Does not interfere with activity (2)'	System	03 Sep 2020 19:52:52

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:24:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-03T15:52:30', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'ef44d726-e452-4cb5-ab55-82089ef0e264'	System	03 Sep 2020 19:52:52
User entered 'No (N)'	System	03 Sep 2020 19:52:52

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-03T15:52:34', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'ef44d726-e452-4cb5-ab55-82089ef0e264'	System	03 Sep 2020 19:52:52
User entered 'No (N)'	System	03 Sep 2020 19:52:52

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:24:53

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 (b99ae654c582cef3)', Time: '2020-09-03T15:52:41', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'ef44d726-e452-4cb5-ab55-82089ef0e264'	System	03 Sep 2020 19:52:52
User entered 'None (1)'	System	03 Sep 2020 19:52:52

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:24:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-03T15:52:50', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'ef44d726-e452-4cb5-ab55-82089ef0e264'	System	03 Sep 2020 19:52:52
User entered '03 Sep 2020 15:52'	System	03 Sep 2020 19:52:52

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:24:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:24:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 14:20:48
User entered 'Day 3'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:24:53

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 (b99ae654c582cef3)', Time: '2020-09-04T16:19:19', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '44b15140-a8d1-45eb-8383-52e7bd1cddcd'	System	04 Sep 2020 20:21:09
User entered 'Does not interfere with activity (2)'	System	04 Sep 2020 20:21:09

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:24:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-04T16:19:40', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '44b15140-a8d1-45eb-8383-52e7bd1cddcd'	System	04 Sep 2020 20:21:09
User entered 'Yes (Y)'	System	04 Sep 2020 20:21:09

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:24:53

Please record - REDNESS AT INJECTION SITE (in mm)

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-04T16:20:57', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '44b15140-a8d1-45eb-8383-52e7bd1cddcd' User entered '7'	System	04 Sep 2020 20:21:09

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-04T16:19:45', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '44b15140-a8d1-45eb-8383-52e7bd1cddcd'	System	04 Sep 2020 20:21:09
User entered 'Yes (Y)'	System	04 Sep 2020 20:21:09

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:24:53

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-04T16:19:58', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '44b15140-a8d1-45eb-8383-52e7bd1cddcd' User entered '7'	System	04 Sep 2020 20:21:09

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:24:53

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 (b99ae654c582cef3)', Time: '2020-09-04T16:20:04', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '44b15140-a8d1-45eb-8383-52e7bd1cddcd'	System	04 Sep 2020 20:21:09
User entered 'None (1)'	System	04 Sep 2020 20:21:09

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:24:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-04T16:21:06', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '44b15140-a8d1-45eb-8383-52e7bd1cddcd'	System	04 Sep 2020 20:21:09
User entered '04 Sep 2020 16:21'	System	04 Sep 2020 20:21:09

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:24:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:24:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 14:20:48
User entered 'Day 4'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:24:53

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 (b99ae654c582cef3)', Time: '2020-09-05T16:01:08', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '8b78c5fe-49ab-48e0-bce6-74f269aac741'	System	05 Sep 2020 20:02:00
User entered 'Does not interfere with activity (2)'	System	05 Sep 2020 20:02:00

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:24:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-05T16:01:11', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '8b78c5fe-49ab-48e0-bce6-74f269aac741'	System	05 Sep 2020 20:02:00
User entered 'No (N)'	System	05 Sep 2020 20:02:00

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-05T16:01:35', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '8b78c5fe-49ab-48e0-bce6-74f269aac741'	System	05 Sep 2020 20:02:00
User entered 'No (N)'	System	05 Sep 2020 20:02:00

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:24:53

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 (b99ae654c582cef3)', Time: '2020-09-05T16:01:49', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '8b78c5fe-49ab-48e0-bce6-74f269aac741'	System	05 Sep 2020 20:02:00
User entered 'None (1)'	System	05 Sep 2020 20:02:00

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:24:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-05T16:01:55', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '8b78c5fe-49ab-48e0-bce6-74f269aac741'	System	05 Sep 2020 20:02:00
User entered '05 Sep 2020 16:01'	System	05 Sep 2020 20:02:00

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:24:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:24:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 14:20:48
User entered 'Day 5'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:24:53

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 (b99ae654c582cef3)', Time: '2020-09-06T17:31:30', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '1ef45747-5eac-4d40-85f3-c5eb5e588161'	System	06 Sep 2020 21:31:46
User entered 'None (1)'	System	06 Sep 2020 21:31:46

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:24:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-06T17:31:32', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '1ef45747-5eac-4d40-85f3-c5eb5e588161'	System	06 Sep 2020 21:31:46
User entered 'No (N)'	System	06 Sep 2020 21:31:46

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-06T17:31:36', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '1ef45747-5eac-4d40-85f3-c5eb5e588161'	System	06 Sep 2020 21:31:46
User entered 'No (N)'	System	06 Sep 2020 21:31:46

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:24:53

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 (b99ae654c582cef3)', Time: '2020-09-06T17:31:40', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '1ef45747-5eac-4d40-85f3-c5eb5e588161'	System	06 Sep 2020 21:31:46
User entered 'None (1)'	System	06 Sep 2020 21:31:46

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:24:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-06T17:31:43', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '1ef45747-5eac-4d40-85f3-c5eb5e588161'	System	06 Sep 2020 21:31:46
User entered '06 Sep 2020 17:31'	System	06 Sep 2020 21:31:46

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:24:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:24:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 14:20:48
User entered 'Day 6'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:24:53

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 (b99ae654c582cef3)', Time: '2020-09-07T15:43:40', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '904d63ea-33e7-4c10-af29-3f254396da3d'	System	07 Sep 2020 19:44:14
User entered 'None (1)'	System	07 Sep 2020 19:44:14

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:24:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-07T15:43:44', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '904d63ea-33e7-4c10-af29-3f254396da3d'	System	07 Sep 2020 19:44:14
User entered 'No (N)'	System	07 Sep 2020 19:44:14

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-07T15:43:59', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '904d63ea-33e7-4c10-af29-3f254396da3d'	System	07 Sep 2020 19:44:14
User entered 'No (N)'	System	07 Sep 2020 19:44:14

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:24:53

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 (b99ae654c582cef3)', Time: '2020-09-07T15:44:04', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '904d63ea-33e7-4c10-af29-3f254396da3d'	System	07 Sep 2020 19:44:14
User entered 'None (1)'	System	07 Sep 2020 19:44:14

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:24:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-07T15:44:12', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '904d63ea-33e7-4c10-af29-3f254396da3d'	System	07 Sep 2020 19:44:14
User entered '07 Sep 2020 15:44'	System	07 Sep 2020 19:44:14

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:24:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:24:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 14:20:48
User entered 'Day 7'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:24:53

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 (b99ae654c582cef3)', Time: '2020-09-08T15:53:51', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'da2e77c2-a17b-487d-a245-e8b96ae6eb92'	System	08 Sep 2020 19:54:17
User entered 'None (1)'	System	08 Sep 2020 19:54:17

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:24:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-08T15:53:54', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'da2e77c2-a17b-487d-a245-e8b96ae6eb92'	System	08 Sep 2020 19:54:17
User entered 'No (N)'	System	08 Sep 2020 19:54:17

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-08T15:53:57', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'da2e77c2-a17b-487d-a245-e8b96ae6eb92'	System	08 Sep 2020 19:54:17
User entered 'No (N)'	System	08 Sep 2020 19:54:17

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:24:53

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 (b99ae654c582cef3)', Time: '2020-09-08T15:54:06', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'da2e77c2-a17b-487d-a245-e8b96ae6eb92'	System	08 Sep 2020 19:54:17
User entered 'None (1)'	System	08 Sep 2020 19:54:17

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:24:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-08T15:54:14', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'da2e77c2-a17b-487d-a245-e8b96ae6eb92'	System	08 Sep 2020 19:54:17
User entered '08 Sep 2020 15:54'	System	08 Sep 2020 19:54:17

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:24:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:24:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 14:20:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-02T10:51:06', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '60bf15ed-3cd5-4f6c-9b75-304560e41723'	System	02 Sep 2020 14:51:37
User entered 'None (0)'	System	02 Sep 2020 14:51:37

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-02T10:51:10', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '60bf15ed-3cd5-4f6c-9b75-304560e41723'	System	02 Sep 2020 14:51:37
User entered 'None (0)'	System	02 Sep 2020 14:51:37

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-02T10:51:12', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '60bf15ed-3cd5-4f6c-9b75-304560e41723'	System	02 Sep 2020 14:51:37
User entered 'None (0)'	System	02 Sep 2020 14:51:37

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-02T10:51:15', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '60bf15ed-3cd5-4f6c-9b75-304560e41723'	System	02 Sep 2020 14:51:37
User entered 'None (0)'	System	02 Sep 2020 14:51:37

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-02T10:51:17', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '60bf15ed-3cd5-4f6c-9b75-304560e41723'	System	02 Sep 2020 14:51:37
User entered 'None (0)'	System	02 Sep 2020 14:51:37

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-02T10:51:20', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '60bf15ed-3cd5-4f6c-9b75-304560e41723'	System	02 Sep 2020 14:51:37
User entered 'None (0)'	System	02 Sep 2020 14:51:37

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

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 (b99ae654c582cef3)', Time: '2020-09-02T10:51:26', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '60bf15ed-3cd5-4f6c-9b75-304560e41723'	System	02 Sep 2020 14:51:37
User entered 'No (N)'	System	02 Sep 2020 14:51:37

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-02T10:51:33', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '60bf15ed-3cd5-4f6c-9b75-304560e41723'	System	02 Sep 2020 14:51:37
User entered '02 Sep 2020 10:51'	System	02 Sep 2020 14:51:37

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 10:33'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:24:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 13:03'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 14:20:48
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-02T15:40:15', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '3db8df7a-1249-4b95-8933-a086e3d52a87'	System	02 Sep 2020 19:40:53
User entered 'None (0)'	System	02 Sep 2020 19:40:53

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-02T15:40:18', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '3db8df7a-1249-4b95-8933-a086e3d52a87'	System	02 Sep 2020 19:40:53
User entered 'None (0)'	System	02 Sep 2020 19:40:53

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-02T15:40:21', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '3db8df7a-1249-4b95-8933-a086e3d52a87'	System	02 Sep 2020 19:40:53
User entered 'None (0)'	System	02 Sep 2020 19:40:53

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-02T15:40:23', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '3db8df7a-1249-4b95-8933-a086e3d52a87'	System	02 Sep 2020 19:40:53
User entered 'None (0)'	System	02 Sep 2020 19:40:53

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-02T15:40:28', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '3db8df7a-1249-4b95-8933-a086e3d52a87'	System	02 Sep 2020 19:40:53
User entered 'None (0)'	System	02 Sep 2020 19:40:53

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-02T15:40:31', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '3db8df7a-1249-4b95-8933-a086e3d52a87'	System	02 Sep 2020 19:40:53
User entered 'None (0)'	System	02 Sep 2020 19:40:53

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

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 (b99ae654c582cef3)', Time: '2020-09-02T15:40:41', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '3db8df7a-1249-4b95-8933-a086e3d52a87'	System	02 Sep 2020 19:40:53
User entered 'No (N)'	System	02 Sep 2020 19:40:53

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-02T15:40:48', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '3db8df7a-1249-4b95-8933-a086e3d52a87'	System	02 Sep 2020 19:40:53
User entered '02 Sep 2020 15:40'	System	02 Sep 2020 19:40:53

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 13:58'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:24:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 14:20:48
User entered 'Day 2'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:24:53

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-03T15:53:04', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'c152f7ff-97c2-4819-b551-0031c7c1f37d'	System	03 Sep 2020 19:54:34
User entered 'No interference with activity (1)'	System	03 Sep 2020 19:54:34

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:24:53

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-03T15:53:14', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'c152f7ff-97c2-4819-b551-0031c7c1f37d'	System	03 Sep 2020 19:54:34
User entered 'None (0)'	System	03 Sep 2020 19:54:34

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:24:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-03T15:53:33', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'c152f7ff-97c2-4819-b551-0031c7c1f37d'	System	03 Sep 2020 19:54:34
User entered 'No interference with activity (1)'	System	03 Sep 2020 19:54:34

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:24:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-03T15:53:38', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'c152f7ff-97c2-4819-b551-0031c7c1f37d'	System	03 Sep 2020 19:54:34
User entered 'None (0)'	System	03 Sep 2020 19:54:34

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:24:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-03T15:53:43', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'c152f7ff-97c2-4819-b551-0031c7c1f37d'	System	03 Sep 2020 19:54:34
User entered 'None (0)'	System	03 Sep 2020 19:54:34

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:24:53

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-03T15:54:16', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'c152f7ff-97c2-4819-b551-0031c7c1f37d'	System	03 Sep 2020 19:54:34
User entered 'No interference with activity (1)'	System	03 Sep 2020 19:54:34

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:24:53

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 (b99ae654c582cef3)', Time: '2020-09-03T15:54:22', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'c152f7ff-97c2-4819-b551-0031c7c1f37d'	System	03 Sep 2020 19:54:34
User entered 'No (N)'	System	03 Sep 2020 19:54:34

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:24:53

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-03T15:54:31', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'c152f7ff-97c2-4819-b551-0031c7c1f37d'	System	03 Sep 2020 19:54:34
User entered '03 Sep 2020 15:54'	System	03 Sep 2020 19:54:34

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:24:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:24:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 14:20:48
User entered 'Day 3'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:24:53

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-04T16:21:14', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '1d264dcf-c989-4864-872e-48b54aabb7b9'	System	04 Sep 2020 20:21:50
User entered 'None (0)'	System	04 Sep 2020 20:21:50

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:24:53

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-04T16:21:18', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '1d264dcf-c989-4864-872e-48b54aabb7b9'	System	04 Sep 2020 20:21:50
User entered 'None (0)'	System	04 Sep 2020 20:21:50

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:24:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-04T16:21:20', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '1d264dcf-c989-4864-872e-48b54aabb7b9'	System	04 Sep 2020 20:21:50
User entered 'None (0)'	System	04 Sep 2020 20:21:50

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:24:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-04T16:21:23', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '1d264dcf-c989-4864-872e-48b54aabb7b9'	System	04 Sep 2020 20:21:50
User entered 'None (0)'	System	04 Sep 2020 20:21:50

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:24:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-04T16:21:26', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '1d264dcf-c989-4864-872e-48b54aabb7b9'	System	04 Sep 2020 20:21:50
User entered 'None (0)'	System	04 Sep 2020 20:21:50

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:24:53

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-04T16:21:30', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '1d264dcf-c989-4864-872e-48b54aabb7b9'	System	04 Sep 2020 20:21:50
User entered 'None (0)'	System	04 Sep 2020 20:21:50

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:24:53

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 (b99ae654c582cef3)', Time: '2020-09-04T16:21:38', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '1d264dcf-c989-4864-872e-48b54aabb7b9'	System	04 Sep 2020 20:21:50
User entered 'No (N)'	System	04 Sep 2020 20:21:50

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:24:53

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-04T16:21:48', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '1d264dcf-c989-4864-872e-48b54aabb7b9'	System	04 Sep 2020 20:21:50
User entered '04 Sep 2020 16:21'	System	04 Sep 2020 20:21:50

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:24:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:24:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 14:20:48
User entered 'Day 4'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:24:53

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-05T16:02:02', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '40ad90d8-f48a-4459-b570-edd21ef1e3a2'	System	05 Sep 2020 20:02:59
User entered 'None (0)'	System	05 Sep 2020 20:02:59

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:24:53

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-05T16:02:23', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '40ad90d8-f48a-4459-b570-edd21ef1e3a2'	System	05 Sep 2020 20:02:59
User entered 'None (0)'	System	05 Sep 2020 20:02:59

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:24:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-05T16:02:27', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '40ad90d8-f48a-4459-b570-edd21ef1e3a2'	System	05 Sep 2020 20:02:59
User entered 'None (0)'	System	05 Sep 2020 20:02:59

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:24:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-05T16:02:31', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '40ad90d8-f48a-4459-b570-edd21ef1e3a2'	System	05 Sep 2020 20:02:59
User entered 'None (0)'	System	05 Sep 2020 20:02:59

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:24:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-05T16:02:38', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '40ad90d8-f48a-4459-b570-edd21ef1e3a2'	System	05 Sep 2020 20:02:59
User entered 'None (0)'	System	05 Sep 2020 20:02:59

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:24:53

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-05T16:02:41', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '40ad90d8-f48a-4459-b570-edd21ef1e3a2'	System	05 Sep 2020 20:02:59
User entered 'None (0)'	System	05 Sep 2020 20:02:59

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:24:53

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 (b99ae654c582cef3)', Time: '2020-09-05T16:02:50', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '40ad90d8-f48a-4459-b570-edd21ef1e3a2'	System	05 Sep 2020 20:02:59
User entered 'No (N)'	System	05 Sep 2020 20:02:59

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:24:53

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-05T16:02:58', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '40ad90d8-f48a-4459-b570-edd21ef1e3a2'	System	05 Sep 2020 20:02:59
User entered '05 Sep 2020 16:02'	System	05 Sep 2020 20:02:59

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:24:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:24:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 14:20:48
User entered 'Day 5'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:24:53

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-06T17:31:49', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'b63df62c-0450-4f8d-bf64-4c150c9ddd42'	System	06 Sep 2020 21:32:08
User entered 'None (0)'	System	06 Sep 2020 21:32:08

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:24:53

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-06T17:31:52', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'b63df62c-0450-4f8d-bf64-4c150c9ddd42'	System	06 Sep 2020 21:32:08
User entered 'None (0)'	System	06 Sep 2020 21:32:08

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:24:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-06T17:31:54', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'b63df62c-0450-4f8d-bf64-4c150c9ddd42'	System	06 Sep 2020 21:32:08
User entered 'None (0)'	System	06 Sep 2020 21:32:08

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:24:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-06T17:31:57', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'b63df62c-0450-4f8d-bf64-4c150c9ddd42'	System	06 Sep 2020 21:32:08
User entered 'None (0)'	System	06 Sep 2020 21:32:08

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:24:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-06T17:31:59', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'b63df62c-0450-4f8d-bf64-4c150c9ddd42'	System	06 Sep 2020 21:32:08
User entered 'None (0)'	System	06 Sep 2020 21:32:08

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:24:53

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-06T17:32:01', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'b63df62c-0450-4f8d-bf64-4c150c9ddd42'	System	06 Sep 2020 21:32:08
User entered 'None (0)'	System	06 Sep 2020 21:32:08

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:24:53

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 (b99ae654c582cef3)', Time: '2020-09-06T17:32:04', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'b63df62c-0450-4f8d-bf64-4c150c9ddd42'	System	06 Sep 2020 21:32:08
User entered 'No (N)'	System	06 Sep 2020 21:32:08

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:24:53

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-06T17:32:07', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'b63df62c-0450-4f8d-bf64-4c150c9ddd42'	System	06 Sep 2020 21:32:08
User entered '06 Sep 2020 17:32'	System	06 Sep 2020 21:32:08

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:24:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:24:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 14:20:48
User entered 'Day 6'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:24:53

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-07T15:44:17', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'bb62f5dc-7997-4de5-86a2-f62dcf5bab60'	System	07 Sep 2020 19:45:05
User entered 'None (0)'	System	07 Sep 2020 19:45:05

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:24:53

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-07T15:44:25', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'bb62f5dc-7997-4de5-86a2-f62dcf5bab60'	System	07 Sep 2020 19:45:05
User entered 'None (0)'	System	07 Sep 2020 19:45:05

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:24:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-07T15:44:28', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'bb62f5dc-7997-4de5-86a2-f62dcf5bab60'	System	07 Sep 2020 19:45:05
User entered 'None (0)'	System	07 Sep 2020 19:45:05

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:24:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-07T15:44:36', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'bb62f5dc-7997-4de5-86a2-f62dcf5bab60'	System	07 Sep 2020 19:45:05
User entered 'None (0)'	System	07 Sep 2020 19:45:05

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:24:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-07T15:44:38', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'bb62f5dc-7997-4de5-86a2-f62dcf5bab60'	System	07 Sep 2020 19:45:05
User entered 'None (0)'	System	07 Sep 2020 19:45:05

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:24:53

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-07T15:44:41', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'bb62f5dc-7997-4de5-86a2-f62dcf5bab60'	System	07 Sep 2020 19:45:05
User entered 'None (0)'	System	07 Sep 2020 19:45:05

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:24:53

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 (b99ae654c582cef3)', Time: '2020-09-07T15:44:51', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'bb62f5dc-7997-4de5-86a2-f62dcf5bab60'	System	07 Sep 2020 19:45:05
User entered 'No (N)'	System	07 Sep 2020 19:45:05

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:24:53

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-07T15:45:00', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: 'bb62f5dc-7997-4de5-86a2-f62dcf5bab60'	System	07 Sep 2020 19:45:05
User entered '07 Sep 2020 15:45'	System	07 Sep 2020 19:45:05

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:24:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:24:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 14:20:48
User entered 'Day 7'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:24:53

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-08T15:54:19', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '6aa37633-01c7-458a-ba8b-1288e3fa3827'	System	08 Sep 2020 19:55:09
User entered 'None (0)'	System	08 Sep 2020 19:55:09

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:24:53

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-08T15:54:23', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '6aa37633-01c7-458a-ba8b-1288e3fa3827'	System	08 Sep 2020 19:55:09
User entered 'None (0)'	System	08 Sep 2020 19:55:09

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:24:53

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-08T15:54:26', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '6aa37633-01c7-458a-ba8b-1288e3fa3827'	System	08 Sep 2020 19:55:09
User entered 'None (0)'	System	08 Sep 2020 19:55:09

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:24:53

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-08T15:54:32', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '6aa37633-01c7-458a-ba8b-1288e3fa3827'	System	08 Sep 2020 19:55:09
User entered 'None (0)'	System	08 Sep 2020 19:55:09

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:24:53

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-08T15:54:38', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '6aa37633-01c7-458a-ba8b-1288e3fa3827'	System	08 Sep 2020 19:55:09
User entered 'None (0)'	System	08 Sep 2020 19:55:09

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:24:53

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-08T15:54:41', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '6aa37633-01c7-458a-ba8b-1288e3fa3827'	System	08 Sep 2020 19:55:09
User entered 'None (0)'	System	08 Sep 2020 19:55:09

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:24:53

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 (b99ae654c582cef3)', Time: '2020-09-08T15:55:03', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '6aa37633-01c7-458a-ba8b-1288e3fa3827'	System	08 Sep 2020 19:55:09
User entered 'No (N)'	System	08 Sep 2020 19:55:09

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:24:53

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-09-08T15:55:06', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '6aa37633-01c7-458a-ba8b-1288e3fa3827'	System	08 Sep 2020 19:55:09
User entered '08 Sep 2020 15:55'	System	08 Sep 2020 19:55:09

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:24:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 14:20:48

US3432016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:24:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 14:20:48

US3432016

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:08:46
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	12 Sep 2020 12:28:43

US3432016

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:08:46
User entered '9 Sep 2020'	Phoebe Cunningham (b) (4)	12 Sep 2020 12:28:43

US3432016

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:08:46
User entered 'Contact Made (CONTACT MADE)'	Phoebe Cunningham (b) (4)	12 Sep 2020 12:28:43

US3432016

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:08:46
User entered empty.	Phoebe Cunningham (b) (4)	12 Sep 2020 12:28:43

US3432016

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:08:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 19:16:36

US3432016

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:53

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 19:16:36

US3432016

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:08:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 19:23:32

US3432016

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:08:53
User entered '16 Sep 2020'	(b) (4), (b) (6)	16 Sep 2020 19:23:32

US3432016

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:08:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	16 Sep 2020 19:23:32

US3432016

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:08:53
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 19:23:32

US3432016

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:59:45
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	23 Sep 2020 21:34:24

US3432016

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:53

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 21:34:24

US3432016

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:59:41
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	23 Sep 2020 21:37:20

US3432016

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:59:41
User entered '23 Sep 2020'	Julia Klopfer (b) (4) (b) (4)	23 Sep 2020 21:37:20

US3432016

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:59:41
User entered 'Contact Made (CONTACT MADE)'	Julia Klopfer (b) (4) (b) (4)	23 Sep 2020 21:37:20

US3432016

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:59:41
User entered empty.	Julia Klopfer (b) (4) (b) (4)	23 Sep 2020 21:37:20

US3432016

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:59:53
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	23 Sep 2020 21:38:10

US3432016

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:53

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 21:38:10

US3432016

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:24:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:05:54
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	30 Sep 2020 15:17:01

US3432016

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:05:54
User entered '30 Sep 2020'	Julia Klopfer (b) (4) (b) (4)	30 Sep 2020 15:17:01

US3432016

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:05:54
User entered 'Clinic (Clinic)'	Julia Klopfer (b) (4) (b) (4)	30 Sep 2020 15:17:01

US3432016

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:24:53

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	30 Sep 2020 15:17:01

US3432016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:06:35
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	30 Sep 2020 15:17:39

US3432016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:06:35
User entered '30 Sep 2020'	Julia Klopfer (b) (4) (b) (4)	30 Sep 2020 15:17:39

US3432016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:06:35
User entered '10:10'	Julia Klopfer (b) (4) (b) (4)	30 Sep 2020 15:17:39

US3432016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
User entered '30 Sep 2020 10:10'	System	30 Sep 2020 15:17:39

US3432016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:53

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:06:35
User entered '98.0' F	Julia Klopfer (b) (4) (b) (4)	30 Sep 2020 15:17:39

US3432016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:53

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:06:35
User entered 'Oral (Oral)'	Julia Klopfer (b) (4) (b) (4)	30 Sep 2020 15:17:39

US3432016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:53

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:06:35
User entered empty.	Julia Klopfer (b) (4) (b) (4)	30 Sep 2020 15:17:39

US3432016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:06:35
User entered '90'	Julia Klopfer (b) (4) (b) (4)	30 Sep 2020 15:17:39

US3432016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:53

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	30 Sep 2020 15:17:39

US3432016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:06:35
User entered '14'	Julia Klopfer (b) (4) (b) (4)	30 Sep 2020 15:17:39

US3432016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	30 Sep 2020 15:17:39

US3432016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:06:35
User entered '122'	Julia Klopfer (b) (4) (b) (4)	30 Sep 2020 15:17:39

US3432016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Sep 2020 15:17:39

US3432016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:06:35
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	05 Oct 2020 06:19:14
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Bruce Bausk (b) (4) (b) (4)	01 Oct 2020 23:56:14
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		30 Sep 2020 15:17:39
User entered '58'	Julia Klopfer (b) (4) (b) (4)	30 Sep 2020 15:17:39

US3432016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:24:53

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Sep 2020 15:17:39

US3432016

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:24:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:06:45
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	30 Sep 2020 15:18:55

US3432016

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:24:53

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:06:45
User entered empty.	Julia Klopfer (b) (4) (b) (4)	30 Sep 2020 15:18:55

US3432016

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:24:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:06:54
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	30 Sep 2020 15:22:31

US3432016

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:24:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:06:54
User entered '30 Sep 2020'	Julia Klopfer (b) (4) (b) (4)	30 Sep 2020 15:22:31

US3432016

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:24:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:06:54
User entered '10:28'	Julia Klopfer (b) (4) (b) (4)	30 Sep 2020 15:22:31

US3432016

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:24:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 10:28'	System	30 Sep 2020 15:22:31

US3432016

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 17:07:01
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	30 Sep 2020 15:22:37

US3432016

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:53

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 15:22:37

US3432016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 14:09:34
User entered 'Day 64'	System	05 Aug 2020 14:09:34

US3432016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[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 (b99ae654c582cef3)', Time: '2020-10-05T15:53:18', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '37a5d5c0-08ae-447c-be3c-a5fba5a23834'	System	05 Oct 2020 19:53:33
User entered 'No (N)'	System	05 Oct 2020 19:53:33

US3432016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

Have you been exposed to someone with 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 (b99ae654c582cef3)', Time: '2020-10-05T15:53:22', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '37a5d5c0-08ae-447c-be3c-a5fba5a23834'	System	05 Oct 2020 19:53:33
User entered 'No (N)'	System	05 Oct 2020 19:53:33

US3432016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-10-05T15:53:28', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '37a5d5c0-08ae-447c-be3c-a5fba5a23834'	System	05 Oct 2020 19:53:33
User entered '05 Oct 2020 15:53:28'	System	05 Oct 2020 19:53:33

US3432016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 14:09:34
User entered '05 Oct 2020 00:01'	System	05 Aug 2020 14:09:34

US3432016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 14:09:34
User entered '09 Oct 2020 23:59'	System	05 Aug 2020 14:09:34

US3432016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 14:09:34
User entered 'Day 71'	System	05 Aug 2020 14:09:34

US3432016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[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 (b99ae654c582cef3)', Time: '2020-10-12T13:28:43', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '18deab47-c33d-4344-bef4-c43d3b2384c4'	System	12 Oct 2020 17:29:02
User entered 'No (N)'	System	12 Oct 2020 17:29:02

US3432016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

Have you been exposed to someone with 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 (b99ae654c582cef3)', Time: '2020-10-12T13:28:47', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '18deab47-c33d-4344-bef4-c43d3b2384c4'	System	12 Oct 2020 17:29:02
User entered 'No (N)'	System	12 Oct 2020 17:29:02

US3432016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-10-12T13:28:53', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '18deab47-c33d-4344-bef4-c43d3b2384c4'	System	12 Oct 2020 17:29:02
User entered '12 Oct 2020 13:28:53'	System	12 Oct 2020 17:29:02

US3432016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 14:09:34
User entered '12 Oct 2020 00:01'	System	05 Aug 2020 14:09:34

US3432016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 14:09:34
User entered '16 Oct 2020 23:59'	System	05 Aug 2020 14:09:34

US3432016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 14:09:34
User entered 'Day 78'	System	05 Aug 2020 14:09:34

US3432016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 (b99ae654c582cef3)', Time: '2020-10-19T15:52:10', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '616ef493-45e2-42a9-9529-0a6453e29cc1'	System	19 Oct 2020 19:52:23
User entered 'No (N)'	System	19 Oct 2020 19:52:23

US3432016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

Have you been exposed to someone with 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 (b99ae654c582cef3)', Time: '2020-10-19T15:52:15', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '616ef493-45e2-42a9-9529-0a6453e29cc1'	System	19 Oct 2020 19:52:23
User entered 'No (N)'	System	19 Oct 2020 19:52:23

US3432016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-10-19T15:52:19', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '616ef493-45e2-42a9-9529-0a6453e29cc1'	System	19 Oct 2020 19:52:23
User entered '19 Oct 2020 15:52:19'	System	19 Oct 2020 19:52:23

US3432016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 14:09:34
User entered '19 Oct 2020 00:01'	System	05 Aug 2020 14:09:34

US3432016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 14:09:34
User entered '23 Oct 2020 23:59'	System	05 Aug 2020 14:09:34

US3432016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 14:09:34
User entered 'Day 92'	System	05 Aug 2020 14:09:34

US3432016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

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 (b99ae654c582cef3)', Time: '2020-11-02T12:20:38', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '2d8eec52-ef99-4437-af66-2f5ed7b2660e'	System	02 Nov 2020 17:20:59
User entered 'No (N)'	System	02 Nov 2020 17:20:59

US3432016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

Have you been exposed to someone with 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 (b99ae654c582cef3)', Time: '2020-11-02T12:20:41', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '2d8eec52-ef99-4437-af66-2f5ed7b2660e'	System	02 Nov 2020 17:20:59
User entered 'No (N)'	System	02 Nov 2020 17:20:59

US3432016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-11-02T12:20:54', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '2d8eec52-ef99-4437-af66-2f5ed7b2660e'	System	02 Nov 2020 17:20:59
User entered '02 Nov 2020 12:20:54'	System	02 Nov 2020 17:20:59

US3432016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 14:09:34
User entered '02 Nov 2020 00:01'	System	05 Aug 2020 14:09:34

US3432016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 14:09:34
User entered '06 Nov 2020 23:59'	System	05 Aug 2020 14:09:34

US3432016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 14:09:34
User entered 'Day 99'	System	05 Aug 2020 14:09:34

US3432016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[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 (b99ae654c582cef3)', Time: '2020-11-09T12:27:03', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '0cdf9dcb-d4ba-4666-a189-da9169dad7db'	System	09 Nov 2020 17:27:16
User entered 'No (N)'	System	09 Nov 2020 17:27:16

US3432016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

Have you been exposed to someone with 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 (b99ae654c582cef3)', Time: '2020-11-09T12:27:07', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '0cdf9dcb-d4ba-4666-a189-da9169dad7db'	System	09 Nov 2020 17:27:16
User entered 'No (N)'	System	09 Nov 2020 17:27:16

US3432016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-11-09T12:27:12', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '0cdf9dcb-d4ba-4666-a189-da9169dad7db'	System	09 Nov 2020 17:27:16
User entered '09 Nov 2020 12:27:12'	System	09 Nov 2020 17:27:16

US3432016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 14:09:34
User entered '09 Nov 2020 00:01'	System	05 Aug 2020 14:09:34

US3432016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 14:09:34
User entered '13 Nov 2020 23:59'	System	05 Aug 2020 14:09:34

US3432016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 14:09:34
User entered 'Day 106'	System	05 Aug 2020 14:09:34

US3432016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[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 (b99ae654c582cef3)', Time: '2020-11-16T12:01:34', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '28cdc8c2-501a-4468-bc12-12748150ed7e'	System	16 Nov 2020 17:02:06
User entered 'No (N)'	System	16 Nov 2020 17:02:06

US3432016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

Have you been exposed to someone with 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 (b99ae654c582cef3)', Time: '2020-11-16T12:01:40', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '28cdc8c2-501a-4468-bc12-12748150ed7e'	System	16 Nov 2020 17:02:06
User entered 'No (N)'	System	16 Nov 2020 17:02:06

US3432016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-11-16T12:01:43', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '28cdc8c2-501a-4468-bc12-12748150ed7e'	System	16 Nov 2020 17:02:06
User entered '16 Nov 2020 12:01:43'	System	16 Nov 2020 17:02:06

US3432016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 14:09:34
User entered '16 Nov 2020 00:01'	System	05 Aug 2020 14:09:34

US3432016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	05 Aug 2020 14:09:34
User entered '20 Nov 2020 23:59'	System	05 Aug 2020 14:09:34

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '02 Oct 2020 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '06 Oct 2020 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '09 Oct 2020 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '13 Oct 2020 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '16 Oct 2020 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '20 Oct 2020 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '23 Oct 2020 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '27 Oct 2020 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '30 Oct 2020 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '03 Nov 2020 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '06 Nov 2020 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '10 Nov 2020 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '13 Nov 2020 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '17 Nov 2020 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[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 (b99ae654c582cef3)', Time: '2020-11-23T05:52:09', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '86b0f236-17f2-4303-9330-74054cb8f26d'	System	23 Nov 2020 10:52:25
User entered 'No (N)'	System	23 Nov 2020 10:52:25

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

Have you been exposed to someone with 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 (b99ae654c582cef3)', Time: '2020-11-23T05:52:14', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '86b0f236-17f2-4303-9330-74054cb8f26d'	System	23 Nov 2020 10:52:25
User entered 'No (N)'	System	23 Nov 2020 10:52:25

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b99ae654c582cef3)', Time: '2020-11-23T05:52:22', User OID: 'PatientReportedOutcome (US3432016)', ODM File OID: '86b0f236-17f2-4303-9330-74054cb8f26d' User entered '23 Nov 2020 05:52:22'	System	23 Nov 2020 10:52:25
	System	23 Nov 2020 10:52:25

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 13:08:56

US3432016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:24:53

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:08:56
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 13:08:56

US3432016

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 14:12:31

US3432016

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '27 Oct 2020'	(b) (4), (b) (6)	27 Oct 2020 14:12:31

US3432016

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	27 Oct 2020 14:12:31

US3432016

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:24:53

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 14:12:31

US3432016

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Oct 2020 14:12:37

US3432016

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:24:53

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 14:12:37

US3432016

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:24:53

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:50:44
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	11 Sep 2020 14:56:23

US3432016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:53

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per MM, The AE term is a symptom of COVID-19..Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 13:21:28
User closed query 'Per DM CLR: Please note that solicited reactions are only to be reported as AE if it meets AE reporting criteria per protocol. Please review if recorded event meets criteria, Else consider deleting event in AE page and record only in Diary Data. Otherwise provide clarification. (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 13:21:09
Query 'Per MM, The AE term is a symptom of COVID-19..Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' answered with 'fever was solicited event that occurred during reacto period, but not reported in ediary. does not trigger illness visit' (Site from DM).	Jessica Cauley (b) (4)	06 Oct 2020 14:08:58
Query 'Per DM CLR: Please note that solicited reactions are only to be reported as AE if it meets AE reporting criteria per protocol. Please review if recorded event meets criteria, Else consider deleting event in AE page and record only in Diary Data. Otherwise provide clarification. ' answered with 'meet AE criteria. not reported in ediary' (Site from DM).	Jessica Cauley (b) (4)	06 Oct 2020 14:07:59
User opened query 'Per MM, The AE term is a symptom of COVID-19..Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 08:24:28
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:06:49

US3432016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:53

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that solicited reactions are only to be reported as AE if it meets AE reporting criteria per protocol. Please review if recorded event meets criteria, Else consider deleting event in AE page and record only in Diary Data. Otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 07:44:35
User coded data point as SOC: General disorders and administration site conditions, HLGT: Body temperature conditions, HLT: Febrile disorders, PT: Pyrexia, LLT: Fever - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 14:59:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 14:59:36
Data point term sent to Coder	System	11 Sep 2020 14:58:17
User entered 'Fever'	Phoebe Cunningham	11 Sep 2020 14:57:23
	(b) (4)	

US3432016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:06:49
User entered 'No (N)'	Phoebe Cunningham (b) (4)	11 Sep 2020 14:57:23

US3432016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:27:25
Query 'The AE will be a solicited AR since it was in the 7 day post dose period; the subject missed to capture it in the eDiary and hence it was noted as an AE. Please edit response to Yes.' canceled (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 21:27:15
User opened query 'The AE will be a solicited AR since it was in the 7 day post dose period; the subject missed to capture it in the eDiary and hence it was noted as an AE. Please edit response to Yes.' (Site from CRA).	(b) (4), (b) (6)	26 Oct 2020 22:45:39
User closed query 'This is a solicited AR since noted after Dose 2, please check and confirm.' (Site from CRA).	(b) (4), (b) (6)	26 Oct 2020 22:44:15
Query 'This is a solicited AR since noted after Dose 2, please check and confirm.' answered with 'not reported in diary' (Site from CRA).	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:27:26
User opened query 'This is a solicited AR since noted after Dose 2, please check and confirm.' (Site from CRA).	(b) (4), (b) (6)	06 Oct 2020 16:52:54
DataPoint Un-verified.	(b) (4), (b) (6)	06 Oct 2020 16:52:00
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:06:49
User entered 'No (N)'	Phoebe Cunningham (b) (4)	11 Sep 2020 14:57:23

US3432016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:06:49
User entered 'No (N)'	Phoebe Cunningham (b) (4)	11 Sep 2020 14:57:23

US3432016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:06:49
User entered '3 Sep 2020'	Phoebe Cunningham (b) (4)	11 Sep 2020 14:57:23

US3432016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:53

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:06:49
User entered '00:00'	Phoebe Cunningham (b) (4)	11 Sep 2020 14:57:23

US3432016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:53

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '3 Sep 2020 00:00'	System	11 Sep 2020 14:57:23

US3432016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:06:49
User entered 'No (N)'	Phoebe Cunningham (b) (4)	11 Sep 2020 14:57:23

US3432016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:53

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:06:49
User entered '4 Sep 2020'	Phoebe Cunningham (b) (4)	11 Sep 2020 14:57:23

US3432016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:53

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:06:49
User closed query 'Per CDM: If AE did not occur within 24 hours of dosage, please remove data from Start Time field. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 08:52:57
Query 'Per CDM: If AE did not occur within 24 hours of dosage, please remove data from Start Time field. ' answered with 'AE occurred within 24 hours of dosage.' (Site from DM).	Jun Bai Park Chang (b) (4)	15 Sep 2020 20:33:38
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	14 Sep 2020 11:40:26
User opened query 'Per CDM: If AE did not occur within 24 hours of dosage, please remove data from Start Time field. ' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 11:40:24
Query 'Data is required. Please provide.' answered with 'not within 24 hrs of dosage' (Site from System).	Phoebe Cunningham (b) (4)	11 Sep 2020 14:57:36
User opened query 'Data is required. Please provide.' (Site from System).	System	11 Sep 2020 14:57:23
User entered empty.	Phoebe Cunningham (b) (4)	11 Sep 2020 14:57:23

US3432016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:53

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 14:57:23

US3432016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:53

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:06:49
User entered 'Grade 1/Mild (Grade 1/Mild)'	Phoebe Cunningham (b) (4)	11 Sep 2020 14:57:23

US3432016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:53

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:06:49
User entered 'No (N)'	Phoebe Cunningham (b) (4)	11 Sep 2020 14:57:23

US3432016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:53

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:06:49
User entered '0'	Phoebe Cunningham (b) (4)	11 Sep 2020 14:57:23

US3432016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:53

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:06:49
User entered '0'	Phoebe Cunningham (b) (4)	11 Sep 2020 14:57:23

US3432016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:06:49
User entered '0'	Phoebe Cunningham (b) (4)	11 Sep 2020 14:57:23

US3432016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:53

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:06:49
User entered empty.	Phoebe Cunningham (b) (4)	11 Sep 2020 14:57:23

US3432016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:53

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:06:49
User entered empty.	Phoebe Cunningham (b) (4)	11 Sep 2020 14:57:23

US3432016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:53

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:06:49
User entered empty.	Phoebe Cunningham (b) (4)	11 Sep 2020 14:57:23

US3432016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:53

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:06:49
User entered empty.	Phoebe Cunningham (b) (4)	11 Sep 2020 14:57:23

US3432016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:06:49
User entered '0'	Phoebe Cunningham (b) (4)	11 Sep 2020 14:57:23

US3432016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:06:49
User entered '0'	Phoebe Cunningham (b) (4)	11 Sep 2020 14:57:23

US3432016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:53

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:06:49
User entered '0'	Phoebe Cunningham (b) (4)	11 Sep 2020 14:57:23

US3432016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:53

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:06:49
User entered 'Related (RELATED)'	Phoebe Cunningham (b) (4)	11 Sep 2020 14:57:23

US3432016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:06:49
User entered 'Not Related (NOT RELATED)'	Phoebe Cunningham (b) (4)	11 Sep 2020 14:57:23

US3432016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:53

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:06:49
User entered 'None (NONE)'	Phoebe Cunningham (b) (4)	11 Sep 2020 14:57:23

US3432016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:53

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:06:49
User entered '0'	Phoebe Cunningham (b) (4)	11 Sep 2020 14:57:23

US3432016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:06:49
User entered '1'	Phoebe Cunningham (b) (4)	11 Sep 2020 14:57:23

US3432016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:06:49
User entered '0'	Phoebe Cunningham (b) (4)	11 Sep 2020 14:57:23

US3432016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:53

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:06:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Phoebe Cunningham (b) (4)	11 Sep 2020 14:57:23

US3432016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:53

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:06:49
User entered empty.	Phoebe Cunningham (b) (4)	11 Sep 2020 14:57:23

US3432016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:53

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 19:06:49
User entered empty.	Phoebe Cunningham (b) (4)	11 Sep 2020 14:57:23

US3432016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:53

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	11 Sep 2020 14:57:23

US3432016

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:24:53

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	11 Sep 2020 14:57:23

US3432016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:24:53

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:09:30
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:48:57
User entered 'USA-US078-2020-mRNA-1273-P301000008'	System	26 Oct 2020 20:48:42
User entered 'New'	(b) (4), (b) (6)	26 Oct 2020 20:48:42

US3432016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:24:53

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:09:30
User closed query 'PV Query: Please split the reported event term into two separate SAEs.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 19:32:02
User closed query 'PV Query: The reported events appear to be signs and symptoms. Please consider updating the event term to the final diagnosis.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 19:31:46
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: GERD - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 21:40:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 21:40:33
Data point term sent to Coder	System	05 Nov 2020 21:39:41
Query 'PV Query: The reported events appear to be signs and symptoms. Please consider updating the event term to the final diagnosis.' answered with 'updated term' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	05 Nov 2020 21:39:15
User entered 'GERD' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	05 Nov 2020 21:39:00
Query 'PV Query: Please split the reported event term into two separate SAEs.' answered with 'not splitting into two, this is one event' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	05 Nov 2020 21:33:28
User opened query 'PV Query: Please split the reported event term into two separate SAEs.' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 20:04:44
User opened query 'PV Query: The reported events appear to be signs and symptoms. Please consider updating the event term to the final diagnosis.' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 20:04:26
Data point term sent to Coder	System	28 Oct 2020 15:21:36
User closed query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms.' (Site from System).	System	28 Oct 2020 15:20:49
Query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms.' answered with 'this was one event' (Site from System).	Monica Feeley (b) (4) (b) (4)	28 Oct 2020 15:20:49

v6.020 DTW (1102)

1779 of 2438

US3432016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:24:53

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' (Site from System). Data point term sent to Coder	Coder Import (b) (4) (b) (4)	26 Oct 2020 18:25:23
User entered 'Epigastric pain and nausea'	System Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:32:01 24 Oct 2020 13:31:22

US3432016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:24:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:09:30
User entered 'Yes (Y)'	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:31:22

US3432016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:24:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:09:30
User entered 'No (N)'	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:31:22

US3432016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:24:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:09:30
User entered 'No (N)'	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:31:22

US3432016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:09:30
User entered '22 Oct 2020'	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:31:22

US3432016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:24:53

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:09:30
User entered empty.	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:31:22

US3432016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:24:53

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Oct 2020 13:31:22

US3432016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:24:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:09:30
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	05 Nov 2020 21:33:03
User entered 'No (N)' reason for change: New Information	Monica Feeley (b) (4)	05 Nov 2020 21:33:03
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	(b) (4)	05 Nov 2020 21:32:48
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	24 Oct 2020 13:31:22
	(b) (4)	

US3432016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:24:53

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:09:30
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 19:32:22
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated' (Site from Safety).	Monica Feeley (b) (4)	05 Nov 2020 21:33:14
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	05 Nov 2020 21:32:48
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	05 Nov 2020 21:32:48
User entered '24 Oct 2020' reason for change: New Information	Monica Feeley (b) (4)	05 Nov 2020 21:32:48
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	05 Nov 2020 21:31:17
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 20:04:04
User entered empty.	Bruce Bausk (b) (4)	24 Oct 2020 13:31:22

US3432016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:24:53

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:09:30
User entered empty.	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:31:22

US3432016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:24:53

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Oct 2020 13:31:22

US3432016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:24:53

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:09:30
User entered 'Grade 3/Severe (Grade 3/Severe)'	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:31:22

US3432016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:24:53

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:09:30
User entered 'Yes (Y)'	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:31:22

US3432016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:24:53

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:09:30
User entered '0'	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:31:22

US3432016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:24:53

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:09:30
User entered '0'	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:31:22

US3432016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:24:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:09:30
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)	04 Nov 2020 10:59:09
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 'currently admitted at time of entry.' (Site from System).	Bruce Bausk (b) (4)	24 Oct 2020 13:31:38
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	24 Oct 2020 13:31:22
User entered '1'	Bruce Bausk (b) (4)	24 Oct 2020 13:31:22

US3432016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:24:53

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'PV Query: As the subject was discharged on the same day as admission, please consider updating serious criteria to medically important event. ' canceled (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 23:58:35
User opened query 'PV Query: As the subject was discharged on the same day as admission, please consider updating serious criteria to medically important event. ' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 15:20:13
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:09:30
User entered '24 Oct 2020'	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:31:22

US3432016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:24:53

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:09:30
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 19:32:38
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'updated' (Site from Safety).	Monica Feeley (b) (4)	05 Nov 2020 21:32:31
User entered '24 Oct 2020' reason for change: Data Entry Error	Monica Feeley (b) (4)	05 Nov 2020 21:32:24
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 20:05:07
User entered empty.	Bruce Bausk (b) (4)	24 Oct 2020 13:31:22

US3432016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:24:53

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:09:30
User entered 'No (N)'	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:31:22

US3432016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:24:53

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:09:30
User entered empty.	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:31:22

US3432016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:24:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:09:30
User entered '0'	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:31:22

US3432016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:24:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:09:30
User entered '0'	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:31:22

US3432016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:24:53

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:09:30
User entered '0'	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:31:22

US3432016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:24:53

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:09:30
User entered 'Not Related (NOT RELATED)'	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:31:22

US3432016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:24:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:09:30
User entered 'Not Related (NOT RELATED)'	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:31:22

US3432016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:24:53

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:09:30
User entered 'Not Applicable (NOT APPLICABLE)'	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:31:22

US3432016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:24:53

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:09:30
User entered '0'	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:31:22

US3432016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:24:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:09:30
User entered '1'	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:31:22

US3432016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:24:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:09:30
User entered '0'	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:31:22

US3432016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:24:53

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:09:30
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 19:32:50
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	Monica Feeley (b) (4)	05 Nov 2020 21:31:30
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Monica Feeley (b) (4)	05 Nov 2020 21:31:17
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 20:05:23
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Bruce Bausk (b) (4)	24 Oct 2020 13:31:22

US3432016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:24:53

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:09:30
User entered empty.	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:31:22

US3432016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:24:53

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Safety Medical Query: The subject was found to have atrial fibrillation. Please consider reporting additional SAE atrial fibrillation. ' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 15:22:15
Query 'Safety Medical Query: The subject was found to have atrial fibrillation. Please consider reporting additional SAE atrial fibrillation. ' answered with 'please note atrial fibrillation is recorded in medical history, thus not as SAE' (Site from Safety).	Monica Feeley (b) (4)	20 Nov 2020 15:44:55
User opened query 'Safety Medical Query: The subject was found to have atrial fibrillation. Please consider reporting additional SAE atrial fibrillation. ' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 15:20:35
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 14:25:28
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'sent' (Site from Safety).	Monica Feeley (b) (4)	10 Nov 2020 21:16:30
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 21:09:30
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 19:33:01
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with '23OCT2020 COVID-19 NP swab negative' (Site from Safety).	Monica Feeley (b) (4)	05 Nov 2020 21:36:15

US3432016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:24:53

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 20:05:59
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 20:05:42
User entered 'Pt consulted to urgent care on 23 oct2020 for epigastric pain, nausea, vomiting and transferred to the ED. Received Zofran and significantly improved. In the context of the GI illness, was also found to have rapid a. fib (A-fib already in med hx) for which they received metoprolol IV x1. Was admitted early 24oct2020 for monitoring.'	Bruce Bausk (b) (4)	24 Oct 2020 13:31:22

US3432016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:24:53

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	24 Oct 2020 13:31:22

US3432016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:24:53

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Oct 2020 13:31:22

US3432016

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:24:53

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Oct 2020 13:31:22

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:24:53

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:30:01
User entered 'Yes (Y)' reason for change: Data Entry Error	Xhoi Mitre (b) (4)	18 Aug 2020 21:04:04
DataPoint Un-verified.	(b) (4)	
	Xhoi Mitre (b) (4)	18 Aug 2020 21:02:15
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Xhoi Mitre (b) (4)	18 Aug 2020 21:02:15
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:21:03
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	05 Aug 2020 19:31:08
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:24:53

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: VACCINIUM MACROCARPON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Aug 2020 23:32:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Aug 2020 23:32:22
Data point term sent to Coder	System	18 Aug 2020 21:03:36
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:21
Data point term sent to Coder	System	18 Aug 2020 21:02:33
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:02:29
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: VACCINIUM MACROCARPON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 22:58:03
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 22:58:03
Data point term sent to Coder	System	05 Aug 2020 19:39:43
User entered 'Cranberry supplement'	Julia Klopfer (b) (4)	05 Aug 2020 19:39:01

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:24:53

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:21
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:29
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered 'No (N)'	Julia Klopfer (b) (4)	05 Aug 2020 19:39:01

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:24:53

[Indication](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:21
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:29
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered 'General Health'	Julia Klopfer (b) (4)	05 Aug 2020 19:39:01
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:24:53

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:21
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:29
DataPoint Verified.	Xhoi Mitre (b) (4)	18 Aug 2020 21:02:29
	(b) (4)	
	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered '500'	Julia Klopfer (b) (4)	05 Aug 2020 19:39:01
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:24:53

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:21
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:29
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered 'mg (mg)'	(b) (4), (b) (6)	05 Aug 2020 19:39:01
	Julia Klopfer (b) (4)	
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:24:53

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:21
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:29
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered empty.	(b) (4), (b) (6)	05 Aug 2020 19:39:01
	Julia Klopfer (b) (4)	
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:24:53

[Frequency](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:21
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:29
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered 'twice daily (BID)'	Julia Klopfer (b) (4)	05 Aug 2020 19:39:01
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:24:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:21
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:29
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
	Julia Klopfer (b) (4)	05 Aug 2020 19:39:01
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:24:53

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:21
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:29
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered 'Oral (ORAL)'	Julia Klopfer (b) (4)	05 Aug 2020 19:39:01
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:24:53

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:21
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:29
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered empty.	(b) (4), (b) (6)	05 Aug 2020 19:39:01
	Julia Klopfer (b) (4)	
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:24:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:21
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:02:29
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). DataPoint Verified.	(b) (4), (b) (6)	15 Aug 2020 00:06:44
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing at time of first injection' (Site from System).	Bruce Bausk (b) (4)	11 Aug 2020 00:07:48
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 19:39:01
User entered 'UN UNK 2010'	Julia Klopfer (b) (4)	05 Aug 2020 19:39:01

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:24:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:21
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:29
DataPoint Verified.	Xhoi Mitre (b) (4)	18 Aug 2020 21:02:29
	(b) (4)	
	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered '0'	Julia Klopfer (b) (4)	05 Aug 2020 19:39:01
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:24:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:21
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:29
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	05 Aug 2020 19:39:01

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:24:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:21
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:29
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4)	05 Aug 2020 19:39:01

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:24:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:21
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:29
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered 'No (N)'	Julia Klopfer (b) (4)	05 Aug 2020 19:39:01

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:24:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:21
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:02:29
User entered '2'	System	05 Aug 2020 19:39:01

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:21
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:02:29
User entered '1'	System	05 Aug 2020 19:39:01

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:21
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:02:29
User entered '804 (804)'	System	05 Aug 2020 19:39:01

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:24:53

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: MUCOLYTICS, PRODUCT: ACETYLCYSTEINE, PRODUCTSYNONYM: N ACETYL CYSTEINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Sep 2020 12:48:43
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Sep 2020 12:48:43
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:07:36
User closed query 'Please do not use acronyms, please use entire name of medication/ supplements.' (Site from CRA).	(b) (4), (b) (6)	26 Aug 2020 15:07:34
Data point term sent to Coder	System	18 Aug 2020 21:08:51
User closed query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	System	18 Aug 2020 21:08:39
Query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' answered with 'resolved' (Site from System).	Xhoi Mitre (b) (4)	18 Aug 2020 21:08:39
Query 'Please do not use acronyms, please use entire name of medication/ supplements.' answered with 'resolved' (Site from CRA).	Xhoi Mitre (b) (4)	18 Aug 2020 21:08:23
User entered 'N-Acetyl Cysteine SUPPLEMENT (Acetylcysteine)' reason for change: Per Query Resolution	Xhoi Mitre (b) (4)	18 Aug 2020 21:08:08
Data point term sent to Coder	System	18 Aug 2020 21:03:37
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:27
Data point term sent to Coder	System	18 Aug 2020 21:02:34
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:02:33

v6.020 DTW (1102)

1835 of 2438

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:24:53

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	Coder Import (b) (4)	17 Aug 2020 13:12:05
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	11 Aug 2020 18:34:55
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
	(b) (4), (b) (6)	
User opened query 'Please do not use acronyms, please use entire name of medication/ supplements.' (Site from CRA).	(b) (4), (b) (6)	11 Aug 2020 18:29:04
Data point term sent to Coder	System	05 Aug 2020 19:40:44
User entered 'NAC Supplement'	Julia Klopfer (b) (4)	05 Aug 2020 19:40:36
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:24:53

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:27
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:33
DataPoint Verified.	(b) (4)	11 Aug 2020 18:29:22
User entered 'No (N)'	Julia Klopfer (b) (4)	05 Aug 2020 19:40:36

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:24:53

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 05:28:18
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'no underlying medication condition. this is a supplement that participant stated they use for mucous production.' (Site from DM).	Monica Feeley (b) (4)	05 Oct 2020 16:39:15
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 04:43:13
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:07:46
User closed query 'Please confirm indication, as subject has asthma and subject is taking it orally. Is this correct?' (Site from CRA).	(b) (4), (b) (6)	26 Aug 2020 15:07:45
Query 'Please confirm indication, as subject has asthma and subject is taking it orally. Is this correct?' answered with 'confirmed' (Site from CRA).	Xhoi Mitre (b) (4)	18 Aug 2020 21:08:27
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:27
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:02:33
DataPoint Un-verified.	(b) (4), (b) (6)	11 Aug 2020 18:35:00
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User opened query 'Please confirm indication, as subject has asthma and subject is taking it orally. Is this correct?' (Site from CRA).	(b) (4), (b) (6)	11 Aug 2020 18:34:35

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:24:53

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	11 Aug 2020 18:32:50
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:29:24
User entered 'mucous production'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:40:36

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:24:53

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:27
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:33
DataPoint Verified.	Xhoi Mitre (b) (4)	11 Aug 2020 18:29:27
User entered '600'	(b) (4), (b) (6)	05 Aug 2020 19:40:36
	Julia Klopfer (b) (4)	
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:24:53

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:27
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:33
DataPoint Verified.	(b) (4)	11 Aug 2020 18:29:30
User entered 'mg (mg)'	Julia Klopfer (b) (4)	05 Aug 2020 19:40:36

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:24:53

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:27
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:33
DataPoint Verified.	(b) (4)	11 Aug 2020 18:29:33
User entered empty.	(b) (4), (b) (6)	05 Aug 2020 19:40:36
	Julia Klopfer (b) (4)	
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:24:53

[Frequency](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:27
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:33
DataPoint Verified.	(b) (4)	11 Aug 2020 18:29:35
User entered 'as needed (PRN)'	Julia Klopfer (b) (4)	05 Aug 2020 19:40:36
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:24:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:27
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:33
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered empty.	(b) (4), (b) (6)	05 Aug 2020 19:40:36
	Julia Klopfer (b) (4)	
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:24:53

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:27
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:33
DataPoint Verified.	(b) (4)	11 Aug 2020 18:29:37
User entered 'Oral (ORAL)'	Julia Klopfer (b) (4)	05 Aug 2020 19:40:36

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:24:53

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:27
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:33
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered empty.	(b) (4), (b) (6)	05 Aug 2020 19:40:36
	Julia Klopfer (b) (4)	
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:24:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:40:17
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:27
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Xhoi Mitre (b) (4)	18 Aug 2020 21:02:33
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
	(b) (4), (b) (6)	15 Aug 2020 00:06:47
DataPoint Un-verified.	(b) (4), (b) (6)	11 Aug 2020 18:35:06
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:46
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing at time of first injection' (Site from System).	Bruce Bausk (b) (4)	11 Aug 2020 00:08:06
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 19:40:36
User entered 'UN UNK 2015'	Julia Klopfer (b) (4)	05 Aug 2020 19:40:36
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:24:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:27
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:33
DataPoint Verified.	Xhoi Mitre (b) (4)	11 Aug 2020 18:34:52
User entered '0'	(b) (4), (b) (6)	05 Aug 2020 19:40:36
	Julia Klopfer (b) (4)	
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:24:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:27
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:02:33
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	05 Aug 2020 19:40:36

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:24:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:27
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:33
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4)	05 Aug 2020 19:40:36

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:24:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:27
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:33
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered 'No (N)'	Julia Klopfer (b) (4)	05 Aug 2020 19:40:36

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:24:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:27
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:02:33
User entered empty.	System	05 Aug 2020 19:40:36

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:27
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:02:33
User entered empty.	System	05 Aug 2020 19:40:36

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:27
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:02:33
User entered empty.	System	05 Aug 2020 19:40:36

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:24:53

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:32:20
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:32:20
Data point term sent to Coder	System	18 Aug 2020 21:03:34
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4) (b) (4)	18 Aug 2020 21:03:32
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4) (b) (4)	18 Aug 2020 21:02:38
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	11 Aug 2020 18:34:52
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Aug 2020 20:41:50
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Aug 2020 20:41:50
Data point term sent to Coder	System	05 Aug 2020 19:42:47
User entered 'Fluticasone intranasal'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:42:32

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:24:53

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:32
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:02:38
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'No (N)'	Julia Klopfer (b) (4)	05 Aug 2020 19:42:32

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:24:53

[Indication](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:32
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:38
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered 'Allergic Rhinitis'	Julia Klopfer (b) (4)	05 Aug 2020 19:42:32
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:24:53

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:32
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:38
DataPoint Verified.	Xhoi Mitre (b) (4)	11 Aug 2020 18:34:52
User entered '2'	(b) (4), (b) (6)	05 Aug 2020 19:42:32
	Julia Klopfer (b) (4)	
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:24:53

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:32
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:38
DataPoint Verified.	Xhoi Mitre (b) (4)	11 Aug 2020 18:34:52
User entered 'Other (OTHER)'	(b) (4), (b) (6)	05 Aug 2020 19:42:32
	Julia Klopfer (b) (4)	
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:24:53

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:32
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:38
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered 'Spray'	Julia Klopfer (b) (4)	05 Aug 2020 19:42:32
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:24:53

[Frequency](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:32
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:38
DataPoint Verified.	Xhoi Mitre (b) (4)	11 Aug 2020 18:34:52
User entered 'as needed (PRN)'	(b) (4), (b) (6)	05 Aug 2020 19:42:32
	Julia Klopfer (b) (4)	
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:24:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:32
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:38
DataPoint Verified.	Xhoi Mitre (b) (4)	18 Aug 2020 21:02:38
	(b) (4)	
	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4)	05 Aug 2020 19:42:32
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:24:53

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:32
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:38
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered 'Nasal (NASAL)'	Julia Klopfer (b) (4)	05 Aug 2020 19:42:32
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:24:53

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:32
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:38
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4)	05 Aug 2020 19:42:32
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:24:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:32
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:02:38
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). DataPoint Verified.	(b) (4), (b) (6)	15 Aug 2020 00:06:51
	(b) (4), (b) (6)	11 Aug 2020 18:34:52
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing at time of first injection' (Site from System).	Bruce Bausk (b) (4)	11 Aug 2020 00:08:30
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 19:42:32
User entered 'UN UNK 2010'	Julia Klopfer (b) (4)	05 Aug 2020 19:42:32

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:24:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:32
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:38
DataPoint Verified.	Xhoi Mitre (b) (4)	18 Aug 2020 21:02:38
	(b) (4)	
	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered '0'	Julia Klopfer (b) (4)	05 Aug 2020 19:42:32
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:24:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:32
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:38
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	05 Aug 2020 19:42:32
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:24:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:32
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:38
DataPoint Verified.	Xhoi Mitre (b) (4)	11 Aug 2020 18:34:52
User entered empty.	(b) (4), (b) (6)	05 Aug 2020 19:42:32
	Julia Klopfer (b) (4)	
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:24:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:32
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:38
DataPoint Verified.	Xhoi Mitre (b) (4)	18 Aug 2020 21:02:38
	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'No (N)'	Julia Klopfer (b) (4)	05 Aug 2020 19:42:32
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:24:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:32
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:02:38
User entered empty.	System	05 Aug 2020 19:42:32

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:32
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:02:38
User entered empty.	System	05 Aug 2020 19:42:32

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:32
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:02:38
User entered empty.	System	05 Aug 2020 19:42:32

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:24:53

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 22:02:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 22:02:41
Data point term sent to Coder	System	23 Sep 2020 22:01:52
User entered 'amoxicillin'	Julia Klopfer (b) (4) (b) (4)	23 Sep 2020 22:01:22
DataPoint activated with code reason code Data required.	Julia Klopfer (b) (4) (b) (4)	23 Sep 2020 21:59:58
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4) (b) (4)	18 Aug 2020 21:00:56

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:24:53

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 22:01:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Sep 2020 22:01:29
User entered 'Yes (Y)' reason for change: Data Entry Error	Julia Klopfer (b) (4)	23 Sep 2020 22:01:29
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 22:01:22
User entered empty.	Julia Klopfer (b) (4)	23 Sep 2020 22:01:22
DataPoint activated with code reason code Data required.	Julia Klopfer (b) (4)	23 Sep 2020 21:59:58
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:00:56

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:24:53

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User entered 'dental prophylaxis'	Julia Klopfer (b) (4)	23 Sep 2020 22:01:22
DataPoint activated with code reason code Data required.	Julia Klopfer (b) (4)	23 Sep 2020 21:59:58
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:00:56

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:24:53

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User entered '2000'	Julia Klopfer (b) (4)	23 Sep 2020 22:01:22
DataPoint activated with code reason code Data required.	Julia Klopfer (b) (4)	23 Sep 2020 21:59:58
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:00:56

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:24:53

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User entered 'mg (mg)'	Julia Klopfer (b) (4)	23 Sep 2020 22:01:22
DataPoint activated with code reason code Data required.	Julia Klopfer (b) (4)	23 Sep 2020 21:59:58
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:00:56

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:24:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User entered empty.	Julia Klopfer (b) (4)	23 Sep 2020 22:01:22
DataPoint activated with code reason code Data required.	Julia Klopfer (b) (4)	23 Sep 2020 21:59:58
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:00:56

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:24:53

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User entered 'once (ONCE)'	Julia Klopfer (b) (4)	23 Sep 2020 22:01:22
DataPoint activated with code reason code Data required.	Julia Klopfer (b) (4)	23 Sep 2020 21:59:58
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:00:56

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:24:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User entered empty.	Julia Klopfer (b) (4)	23 Sep 2020 22:01:22
DataPoint activated with code reason code Data required.	Julia Klopfer (b) (4)	23 Sep 2020 21:59:58
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:00:56

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:24:53

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User entered 'Oral (ORAL)'	Julia Klopfer (b) (4)	23 Sep 2020 22:01:22
DataPoint activated with code reason code Data required.	Julia Klopfer (b) (4)	23 Sep 2020 21:59:58
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:00:56

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:24:53

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User entered empty.	Julia Klopfer (b) (4)	23 Sep 2020 22:01:22
DataPoint activated with code reason code Data required.	Julia Klopfer (b) (4)	23 Sep 2020 21:59:58
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:00:56

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User entered '22 Sep 2020'	Julia Klopfer (b) (4)	23 Sep 2020 22:01:22
DataPoint activated with code reason code Data required.	Julia Klopfer (b) (4)	23 Sep 2020 21:59:58
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:00:56

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:24:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User entered '0'	Julia Klopfer (b) (4)	23 Sep 2020 22:01:22
DataPoint activated with code reason code Data required.	Julia Klopfer (b) (4)	23 Sep 2020 21:59:58
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:00:56

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:24:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User entered 'No (N)'	Julia Klopfer (b) (4)	23 Sep 2020 22:01:22
DataPoint activated with code reason code Data required.	Julia Klopfer (b) (4)	23 Sep 2020 21:59:58
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:00:56

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:24:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User entered '22 Sep 2020'	Julia Klopfer (b) (4)	23 Sep 2020 22:01:22
DataPoint activated with code reason code Data required.	Julia Klopfer (b) (4)	23 Sep 2020 21:59:58
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:00:56

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:24:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User entered 'No (N)'	Julia Klopfer (b) (4)	23 Sep 2020 22:01:22
DataPoint activated with code reason code Data required.	Julia Klopfer (b) (4)	23 Sep 2020 21:59:58
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:00:56

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:24:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 22:01:22
DataPoint activated with code reason code Data required.	Julia Klopfer (b) (4) (b) (4)	23 Sep 2020 21:59:58
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4) (b) (4)	18 Aug 2020 21:00:56

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 22:01:22
DataPoint activated with code reason code Data required.	Julia Klopfer (b) (4) (b) (4)	23 Sep 2020 21:59:58
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4) (b) (4)	18 Aug 2020 21:00:56

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 22:01:22
DataPoint activated with code reason code Data required.	Julia Klopfer (b) (4) (b) (4)	23 Sep 2020 21:59:58
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4) (b) (4)	18 Aug 2020 21:00:56

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:24:53

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, PRODUCT: BIOTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Aug 2020 23:32:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Aug 2020 23:32:20
Data point term sent to Coder	System	18 Aug 2020 21:03:38
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:36
Data point term sent to Coder	System	18 Aug 2020 21:03:35
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:02:43
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, PRODUCT: BIOTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 19:46:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 19:46:37
Data point term sent to Coder	System	05 Aug 2020 19:44:53
User entered 'Biotin'	Julia Klopfer (b) (4)	05 Aug 2020 19:44:37

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:24:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Query 'Per CDM re-query: Per previous query, indication recorded may indicate this medication used as prophylaxis. Please review and update as appropriate else clarify.' answered with 'This medication is taken for general health and not for prophylaxis.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 15:17:00
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)	23 Nov 2020 07:12:41
User opened query 'Per CDM re-query: Per previous query, indication recorded may indicate this medication used as prophylaxis. Please review and update as appropriate else clarify.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 07:12:39
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 'not prophylaxis' (Site from DM).	Monica Feeley (b) (4)	12 Nov 2020 18:06:12
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)	12 Nov 2020 17:37:23
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:36
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:02:43
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'No (N)'	Julia Klopfer (b) (4)	05 Aug 2020 19:44:37

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:24:53

[Indication](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:36
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:43
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered 'General Health'	Julia Klopfer (b) (4)	05 Aug 2020 19:44:37
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:24:53

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:36
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:43
DataPoint Verified.	Xhoi Mitre (b) (4)	11 Aug 2020 18:34:52
User entered '3000'	(b) (4), (b) (6)	05 Aug 2020 19:44:37
	Julia Klopfer (b) (4)	
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:24:53

[Dose unit](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 05:30:36
	(b) (4), (b) (6)	06 Oct 2020 16:42:48
Query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' answered with 'updated' (Site from DM). DataPoint Un-verified.	Monica Feeley (b) (4) (b) (4)	05 Oct 2020 16:38:22
	Monica Feeley (b) (4) (b) (4)	05 Oct 2020 16:38:17
User entered 'ug (ug)' reason for change: Per Query Resolution	Monica Feeley (b) (4) (b) (4)	05 Oct 2020 16:38:17
User opened query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	03 Oct 2020 04:28:05
	(b) (4), (b) (6)	23 Sep 2020 18:37:28
DataPoint Un-verified.	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 14:25:55
User entered 'mg (mg)' reason for change: Data Entry Error	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 14:25:55
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4) (b) (4)	18 Aug 2020 21:03:36
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4) (b) (4)	18 Aug 2020 21:02:43
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'ug (ug)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:44:37

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:24:53

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:36
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:43
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4)	05 Aug 2020 19:44:37

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:24:53

[Frequency](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:36
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:43
DataPoint Verified.	Xhoi Mitre (b) (4)	11 Aug 2020 18:34:52
User entered 'once daily (QD)'	(b) (4), (b) (6)	05 Aug 2020 19:44:37
	Julia Klopfer (b) (4)	
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:24:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:36
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:43
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered empty.	(b) (4), (b) (6)	05 Aug 2020 19:44:37
	Julia Klopfer (b) (4)	
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:24:53

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:36
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:02:43
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'Oral (ORAL)'	Julia Klopfer (b) (4)	05 Aug 2020 19:44:37

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:24:53

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:36
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:43
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered empty.	(b) (4), (b) (6)	05 Aug 2020 19:44:37
	Julia Klopfer (b) (4)	
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:24:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:36
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:02:43
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). DataPoint Verified.	(b) (4), (b) (6)	15 Aug 2020 00:07:05
	(b) (4), (b) (6)	11 Aug 2020 18:34:52
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing at time of first injection' (Site from System).	Bruce Bausk (b) (4)	11 Aug 2020 00:09:22
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 19:44:37
User entered 'UN UNK 2017'	Julia Klopfer (b) (4)	05 Aug 2020 19:44:37

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:24:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:36
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:43
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered '0'	Julia Klopfer (b) (4)	05 Aug 2020 19:44:37
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:24:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:36
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:43
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	05 Aug 2020 19:44:37

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:24:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:36
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:43
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered empty.	(b) (4), (b) (6)	05 Aug 2020 19:44:37
	Julia Klopfer (b) (4)	
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:24:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:36
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:43
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered 'No (N)'	Julia Klopfer (b) (4)	05 Aug 2020 19:44:37

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:24:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:36
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:02:43
User entered '1'	System	05 Aug 2020 19:44:37

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:36
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:02:43
User entered '1'	System	05 Aug 2020 19:44:37

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:36
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:02:43
User entered '804 (804)'	System	05 Aug 2020 19:44:37

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:24:53

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, PRODUCT: XANTOFYL, PRODUCTSYNONYM: LUTEIN [XANTOFYL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Aug 2020 23:32:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	18 Aug 2020 23:32:23
Data point term sent to Coder	System	18 Aug 2020 21:04:41
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:42
Data point term sent to Coder	System	18 Aug 2020 21:03:34
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:02:48
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, PRODUCT: XANTOFYL, PRODUCTSYNONYM: LUTEIN [XANTOFYL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 13:21:20
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	(b) (4)	11 Aug 2020 13:21:20
Data point term sent to Coder	System	05 Aug 2020 19:46:55
User entered 'Lutein'	Julia Klopfer (b) (4)	05 Aug 2020 19:46:21
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:24:53

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:42
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:48
DataPoint Verified.	Xhoi Mitre (b) (4)	11 Aug 2020 18:34:52
User entered 'No (N)'	(b) (4), (b) (6)	05 Aug 2020 19:46:21
	Julia Klopfer (b) (4)	
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:24:53

[Indication](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:42
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:02:48
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'General Health'	Julia Klopfer (b) (4)	05 Aug 2020 19:46:21

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:24:53

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:42
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:48
DataPoint Verified.	Xhoi Mitre (b) (4)	11 Aug 2020 18:34:52
User entered '20'	(b) (4), (b) (6)	05 Aug 2020 19:46:21
	Julia Klopfer (b) (4)	
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:24:53

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:42
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:48
DataPoint Verified.	Xhoi Mitre (b) (4)	11 Aug 2020 18:34:52
User entered 'mg (mg)'	(b) (4), (b) (6)	05 Aug 2020 19:46:21
	Julia Klopfer (b) (4)	
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:24:53

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:42
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:48
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered empty.	(b) (4), (b) (6)	05 Aug 2020 19:46:21
	Julia Klopfer (b) (4)	
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:24:53

[Frequency](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:42
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:48
DataPoint Verified.	Xhoi Mitre (b) (4)	11 Aug 2020 18:34:52
User entered 'once daily (QD)'	(b) (4), (b) (6)	05 Aug 2020 19:46:21
	Julia Klopfer (b) (4)	
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:24:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:42
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:48
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4)	05 Aug 2020 19:46:21

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:24:53

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:42
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:48
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered 'Oral (ORAL)'	Julia Klopfer (b) (4)	05 Aug 2020 19:46:21
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:24:53

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:42
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:48
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered empty.	(b) (4), (b) (6)	05 Aug 2020 19:46:21
	Julia Klopfer (b) (4)	
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:24:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:42
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:02:48
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). DataPoint Verified.	(b) (4), (b) (6)	15 Aug 2020 00:07:15
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing at time of first injection' (Site from System).	Bruce Bausk (b) (4)	11 Aug 2020 00:09:38
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 19:46:21
User entered 'UN UNK 2018'	Julia Klopfer (b) (4)	05 Aug 2020 19:46:21

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:24:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:42
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:48
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered '0'	Julia Klopfer (b) (4)	05 Aug 2020 19:46:21
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:24:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:42
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:48
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	05 Aug 2020 19:46:21

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:24:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:42
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:48
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered empty.	(b) (4), (b) (6)	05 Aug 2020 19:46:21
	Julia Klopfer (b) (4)	
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:24:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:42
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:48
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered 'No (N)'	Julia Klopfer (b) (4)	05 Aug 2020 19:46:21

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:24:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:42
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:02:48
User entered '1'	System	05 Aug 2020 19:46:21

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:42
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:02:48
User entered '1'	System	05 Aug 2020 19:46:21

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:42
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:02:48
User entered '804 (804)'	System	05 Aug 2020 19:46:21

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:24:53

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:38:49
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: IMMUNOSUPPRESSANTS, ATC: IMMUNOSUPPRESSANTS, PRODUCT: IMMUNOTHERAPY - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 09:29:40
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 09:29:40
User closed query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening)' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 18:19:40
Query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening)' answered with 'Study physician confirmed that this medication is not a systematic immunosuppressant or immune-modifying drug.' (Site from DM).	Jun Bai Park Chang (b) (4)	11 Sep 2020 19:47:09
Data point term sent to Coder	System	11 Sep 2020 19:45:53
User closed query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' (Site from System).	System	11 Sep 2020 19:45:35
Query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' answered with 'updated' (Site from System).	Jun Bai Park Chang (b) (4)	11 Sep 2020 19:45:35
DataPoint Un-verified.	Jun Bai Park Chang (b) (4)	11 Sep 2020 19:45:15

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:24:53

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Sublingual Immunotherapy Solution (SLIT Solution)' reason for change: Per Query Resolution	Jun Bai Park Chang (b) (4)	11 Sep 2020 19:45:15
User opened query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' (Site from System).	Coder Import (b) (4) (b) (4)	09 Sep 2020 13:37:36
User opened query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening)' (Site from DM).	(b) (4), (b) (6) (b) (4)	04 Sep 2020 09:20:37
Data point term sent to Coder	System	18 Aug 2020 21:04:40
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4) (b) (4)	18 Aug 2020 21:03:47
Data point term sent to Coder	System	18 Aug 2020 21:03:35
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4) (b) (4)	18 Aug 2020 21:02:54
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	11 Aug 2020 18:34:52
Data point term sent to Coder	System	05 Aug 2020 19:48:58
User entered 'SLIT Solution'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:48:24

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:24:53

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:47
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:54
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered 'No (N)'	Julia Klopfer (b) (4)	05 Aug 2020 19:48:24

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:24:53

[Indication](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:47
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:54
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered 'Allergic rhinitis'	Julia Klopfer (b) (4)	05 Aug 2020 19:48:24
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:24:53

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:47
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:54
DataPoint Verified.	Xhoi Mitre (b) (4)	11 Aug 2020 18:34:52
User entered '1'	(b) (4), (b) (6)	05 Aug 2020 19:48:24
	Julia Klopfer (b) (4)	
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:24:53

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:47
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:54
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered 'Other (OTHER)'	Julia Klopfer (b) (4)	05 Aug 2020 19:48:24
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:24:53

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:47
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:54
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered 'pump'	Julia Klopfer (b) (4)	05 Aug 2020 19:48:24
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:24:53

[Frequency](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:47
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:54
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered 'three times daily (TID)'	Julia Klopfer (b) (4)	05 Aug 2020 19:48:24
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:24:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:47
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:54
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered empty.	(b) (4), (b) (6)	05 Aug 2020 19:48:24
	Julia Klopfer (b) (4)	
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:24:53

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:47
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:54
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered 'Other (OTHER)'	Julia Klopfer (b) (4)	05 Aug 2020 19:48:24
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:24:53

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:47
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:54
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered 'sublingual'	Julia Klopfer (b) (4)	05 Aug 2020 19:48:24
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:24:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:47
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:02:54
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). DataPoint Verified.	(b) (4), (b) (6)	15 Aug 2020 00:07:19
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing at time of first injection' (Site from System).	Bruce Bausk (b) (4)	11 Aug 2020 00:10:17
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 19:48:24
User entered '01 May 2020'	Julia Klopfer (b) (4)	05 Aug 2020 19:48:24

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:24:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:47
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:54
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered '0'	(b) (4), (b) (6)	05 Aug 2020 19:48:24
	Julia Klopfer (b) (4)	
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:24:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:47
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:54
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	05 Aug 2020 19:48:24

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:24:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:47
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:54
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered empty.	(b) (4), (b) (6)	05 Aug 2020 19:48:24
	Julia Klopfer (b) (4)	
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:24:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:47
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:02:54
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered 'No (N)'	Julia Klopfer (b) (4)	05 Aug 2020 19:48:24

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:24:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:47
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:02:54
User entered '3'	System	05 Aug 2020 19:48:24

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:47
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:02:54
User entered '1'	System	05 Aug 2020 19:48:24

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:47
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:02:54
User entered '804 (804)'	System	05 Aug 2020 19:48:24

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:24:53

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:32:23
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 Aug 2020 23:32:23
Data point term sent to Coder	System	18 Aug 2020 21:04:41
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4) (b) (4)	18 Aug 2020 21:03:52
Data point term sent to Coder	System	18 Aug 2020 21:03:36
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4) (b) (4)	18 Aug 2020 21:03:00
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 22:28:07
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 22:28:07
Data point term sent to Coder	System	05 Aug 2020 19:49:58
User entered 'Aspirin'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:49:07

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:24:53

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:52
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:00
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'No (N)'	Julia Klopfer (b) (4)	05 Aug 2020 19:49:07

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:24:53

[Indication](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:52
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:03:00
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered 'Atrial fibrillation'	Julia Klopfer (b) (4)	05 Aug 2020 19:49:07

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:24:53

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:08:35
User closed query 'Please check source notes con-med log and confirm if dose is 81mg or 89mg' (Site from CRA).	(b) (4), (b) (6)	26 Aug 2020 15:08:33
Query 'Please check source notes con-med log and confirm if dose is 81mg or 89mg' answered with '81 mg confirmed' (Site from CRA).	Xhoi Mitre (b) (4)	18 Aug 2020 21:09:23
User entered '81' reason for change: Per Query Resolution	(b) (4)	18 Aug 2020 21:09:11
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:52
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:03:00
User opened query 'Please check source notes con-med log and confirm if dose is 81mg or 89mg' (Site from CRA).	Xhoi Mitre (b) (4)	11 Aug 2020 18:39:53
DataPoint Un-verified.	(b) (4), (b) (6)	11 Aug 2020 18:39:08
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered '89'	Julia Klopfer (b) (4)	05 Aug 2020 19:49:07

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:24:53

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:52
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:03:00
DataPoint Verified.	Xhoi Mitre (b) (4)	11 Aug 2020 18:34:52
User entered 'mg (mg)'	(b) (4), (b) (6)	05 Aug 2020 19:49:07
	Julia Klopfer (b) (4)	
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:24:53

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:52
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:03:00
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered empty.	(b) (4), (b) (6)	05 Aug 2020 19:49:07
	Julia Klopfer (b) (4)	
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:24:53

[Frequency](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:52
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:03:00
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered 'once daily (QD)'	Julia Klopfer (b) (4)	05 Aug 2020 19:49:07

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:24:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:52
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:03:00
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4)	05 Aug 2020 19:49:07

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:24:53

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:52
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:03:00
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered 'Oral (ORAL)'	Julia Klopfer (b) (4)	05 Aug 2020 19:49:07

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:24:53

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:52
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:03:00
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered empty.	(b) (4), (b) (6)	05 Aug 2020 19:49:07
	Julia Klopfer (b) (4)	
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:24:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:52
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:00
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). DataPoint Verified.	(b) (4), (b) (6)	15 Aug 2020 00:07:23
	(b) (4), (b) (6)	11 Aug 2020 18:34:52
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing at time of first injection' (Site from System).	Bruce Bausk (b) (4)	11 Aug 2020 00:10:32
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 19:49:07
User entered 'UN UNK 2019'	Julia Klopfer (b) (4)	05 Aug 2020 19:49:07

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:24:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:52
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:03:00
DataPoint Verified.	Xhoi Mitre (b) (4)	11 Aug 2020 18:34:52
User entered '0'	(b) (4), (b) (6)	05 Aug 2020 19:49:07
	Julia Klopfer (b) (4)	
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:24:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:52
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:03:00
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	05 Aug 2020 19:49:07

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:24:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:52
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:03:00
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4)	05 Aug 2020 19:49:07

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:24:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:52
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:03:00
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered 'No (N)'	Julia Klopfer (b) (4)	05 Aug 2020 19:49:07

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:24:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:52
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:00
User entered '1'	System	05 Aug 2020 19:49:07

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:52
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:00
User entered '1'	System	05 Aug 2020 19:49:07

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:52
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:00
User entered '804 (804)'	System	05 Aug 2020 19:49:07

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:24:53

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:32:48
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 Aug 2020 23:32:48
Data point term sent to Coder	System	18 Aug 2020 21:04:41
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4) (b) (4)	18 Aug 2020 21:03:57
Data point term sent to Coder	System	18 Aug 2020 21:03:36
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4) (b) (4)	18 Aug 2020 21:03:05
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	11 Aug 2020 18:34:52
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 19:52:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 19:52:01
Data point term sent to Coder	System	05 Aug 2020 19:50:59
User entered 'Lisinopril'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:50:58

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:24:53

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:57
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:05
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'No (N)'	Julia Klopfer (b) (4)	05 Aug 2020 19:50:58

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:24:53

[Indication](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:57
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:03:05
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered 'Hypertension'	Julia Klopfer (b) (4)	05 Aug 2020 19:50:58

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:24:53

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:57
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:03:05
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered '5'	Julia Klopfer (b) (4)	05 Aug 2020 19:50:58

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:24:53

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:57
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:03:05
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered 'mg (mg)'	Julia Klopfer (b) (4)	05 Aug 2020 19:50:58

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:24:53

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:57
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:03:05
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4)	05 Aug 2020 19:50:58
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:24:53

[Frequency](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:57
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:03:05
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered 'once daily (QD)'	Julia Klopfer (b) (4)	05 Aug 2020 19:50:58

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:24:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:57
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:03:05
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4)	05 Aug 2020 19:50:58

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:24:53

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:57
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:03:05
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered 'Oral (ORAL)'	Julia Klopfer (b) (4)	05 Aug 2020 19:50:58
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:24:53

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:57
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:03:05
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered empty.	(b) (4), (b) (6)	05 Aug 2020 19:50:58
	Julia Klopfer (b) (4)	
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:24:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:57
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:05
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). DataPoint Verified.	(b) (4), (b) (6)	15 Aug 2020 00:07:27
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing at time of first injection' (Site from System).	Bruce Bausk (b) (4)	11 Aug 2020 00:10:50
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 19:50:58
User entered 'UN UNK 2010'	Julia Klopfer (b) (4)	05 Aug 2020 19:50:58

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:24:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:57
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:03:05
DataPoint Verified.	Xhoi Mitre (b) (4)	11 Aug 2020 18:34:52
User entered '0'	(b) (4), (b) (6)	05 Aug 2020 19:50:58
	Julia Klopfer (b) (4)	
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:24:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:57
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:03:05
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	05 Aug 2020 19:50:58

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:24:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:57
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:03:05
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4)	05 Aug 2020 19:50:58

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:24:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:57
DataPoint inactivated with code reason code Data not required.	(b) (4)	18 Aug 2020 21:03:05
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered 'No (N)'	Julia Klopfer (b) (4)	05 Aug 2020 19:50:58

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:24:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:57
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:05
User entered '1'	System	05 Aug 2020 19:50:58

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:57
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	18 Aug 2020 21:03:05
User entered '1'	System	05 Aug 2020 19:50:58

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Definition \(derived\)](#)

Audit	User		Time (GMT)
DataPoint activated with code reason code Data required.	Xhoi Mitre (b) (4)	(b) (4)	18 Aug 2020 21:03:57
DataPoint inactivated with code reason code Data not required.	Xhoi Mitre (b) (4)	(b) (4)	18 Aug 2020 21:03:05
User entered '804 (804)'	System		05 Aug 2020 19:50:58

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:24:53

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 19:56:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 19:56:06
Data point term sent to Coder	System	05 Aug 2020 19:55:06
User entered 'Hydrochlorothiazide'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:54:46

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:24:53

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:54:46

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:24:53

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'Hypertension'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:54:46

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:24:53

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered '50'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:54:46

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:24:53

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:39:54
DataPoint Un-verified.	Julia Klopfer (b) (4)	02 Sep 2020 14:26:22
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4)	02 Sep 2020 14:26:22
DataPoint Verified.	Julia Klopfer (b) (4)	02 Sep 2020 14:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
	(b) (4)	
User entered 'ug (ug)'	Julia Klopfer (b) (4)	05 Aug 2020 19:54:46
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:24:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:54:46

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:24:53

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'once daily (QD)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:54:46

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:24:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:54:46

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:24:53

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'Oral (ORAL)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:54:46

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:24:53

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:54:46

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:24:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). DataPoint Verified.	(b) (4), (b) (6)	15 Aug 2020 00:07:31
	(b) (4), (b) (6)	11 Aug 2020 18:34:52
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing at time of first injection' (Site from System).	Bruce Bausk (b) (4)	11 Aug 2020 00:11:07
	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 19:54:46
User entered 'UN UNK 2010'	Julia Klopfer (b) (4)	05 Aug 2020 19:54:46
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:24:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered '0'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:54:46

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:24:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:54:46

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:24:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:54:46

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:24:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:54:46

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:24:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 19:54:46

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 19:54:46

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 19:54:46

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:24:53

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 14:19:09
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 Aug 2020 14:19:09
Data point term sent to Coder	System	05 Aug 2020 19:57:08
User entered 'Montelukast'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:56:44

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:24:53

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:56:44

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:24:53

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'Allergic rhinitis'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:56:44

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:24:53

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered '10'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:56:44

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:24:53

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'mg (mg)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:56:44

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:24:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:56:44

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:24:53

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'once daily (QD)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:56:44

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:24:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:56:44

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:24:53

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'Oral (ORAL)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:56:44

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:24:53

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:56:44

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:24:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). DataPoint Verified.	(b) (4), (b) (6)	15 Aug 2020 00:07:35
	(b) (4), (b) (6)	11 Aug 2020 18:34:52
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing at time of first injection' (Site from System).	Bruce Bausk (b) (4) (b) (4)	11 Aug 2020 00:11:21
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 19:56:44
User entered 'UN UNK 2010'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:56:44

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:24:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered '0'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:56:44

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:24:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:56:44

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:24:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:56:44

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:24:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 19:56:44

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:24:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 19:56:44

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 19:56:44

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 19:56:44

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:24:53

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 20:04:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 20:04:01
Data point term sent to Coder	System	05 Aug 2020 20:03:13
User entered 'Simvastatin'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:02:31

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:24:53

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:02:31

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:24:53

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'Hyperlipidemia'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:02:31

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:24:53

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered '20'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:02:31

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:24:53

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
DataPoint Un-verified.	Julia Klopfer (b) (4)	02 Sep 2020 14:26:41
User entered 'mg (mg)' reason for change: Data Entry Error	Julia Klopfer (b) (4)	02 Sep 2020 14:26:41
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'ug (ug)'	Julia Klopfer (b) (4)	05 Aug 2020 20:02:31

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:24:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:02:31

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:24:53

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'once daily (QD)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:02:31

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:24:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:02:31

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:24:53

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'Oral (ORAL)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:02:31

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:24:53

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:02:31

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:24:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). DataPoint Verified.	(b) (4), (b) (6)	15 Aug 2020 00:07:38
	(b) (4), (b) (6)	11 Aug 2020 18:34:52
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing at time of first injection' (Site from System).	Bruce Bausk (b) (4) (b) (4)	11 Aug 2020 00:11:34
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 20:03:02
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	05 Aug 2020 20:03:02
User entered 'UN UNK 2012' reason for change: Data Entry Error	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:03:02
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	05 Aug 2020 20:02:31
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:02:31

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:24:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered '0'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:02:31

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:24:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Aug 2020 20:03:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Aug 2020 20:03:02
User entered 'Yes (Y)' reason for change: Data Entry Error	Julia Klopfer (b) (4)	05 Aug 2020 20:03:02
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Aug 2020 20:02:31
User entered empty.	Julia Klopfer (b) (4)	05 Aug 2020 20:02:31

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:24:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:02:31

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:24:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Aug 2020 20:03:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Aug 2020 20:03:02
User entered 'No (N)' reason for change: Data Entry Error	Julia Klopfer (b) (4)	05 Aug 2020 20:03:02
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Aug 2020 20:02:31
User entered empty.	Julia Klopfer (b) (4)	05 Aug 2020 20:02:31

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:24:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 20:02:31

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 20:02:31

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 20:02:31

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:24:53

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, PRODUCT: CICLOSPORIN, PRODUCTSYNONYM: RESTASIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 07:22:08
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 07:22:08
Data point term sent to Coder Coding entries removed.	System Julia Klopfer (b) (4) (b) (4)	06 Nov 2020 18:48:20 06 Nov 2020 18:48:17
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, ATC: OTHER OPHTHALMOLOGICALS, PRODUCT: CICLOSPORIN, PRODUCTSYNONYM: RESTASIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:33:18
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 18:33:18
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	11 Aug 2020 18:34:52
Data point term sent to Coder User entered 'Restasis eye drops'	System Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:05:18 05 Aug 2020 20:04:37

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:24:53

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:04:37

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:24:53

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'not medical history' (Site from DM).	Monica Feeley (b) (4)	10 Nov 2020 21:06:35
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 08:53:12
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'Dry eyes'	Julia Klopfer (b) (4)	05 Aug 2020 20:04:37
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:24:53

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered '2'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:04:37

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:24:53

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'Other (OTHER)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:04:37

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:24:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'drops'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:04:37

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:24:53

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'twice daily (BID)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:04:37

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:24:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:04:37

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:24:53

[Route of administration](#)

Audit	User	Time (GMT)
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)	23 Nov 2020 07:08:20
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:56:02
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'updated' (Site from DM).	Julia Klopfer (b) (4)	06 Nov 2020 18:48:26
DataPoint Un-verified.	Julia Klopfer (b) (4)	06 Nov 2020 18:48:17
User entered 'Other (OTHER)' reason for change: Data Entry Error	Julia Klopfer (b) (4)	06 Nov 2020 18:48:17
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)	22 Oct 2020 08:53:23
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'Intraocular (INTRAOCULAR)'	Julia Klopfer (b) (4)	05 Aug 2020 20:04:37

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:24:53

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:56:02
DataPoint Un-verified.	Julia Klopfer (b) (4)	06 Nov 2020 18:48:17
User entered 'ocular' reason for change: Data Entry Error	(b) (4)	06 Nov 2020 18:48:17
DataPoint Verified.	Julia Klopfer (b) (4)	06 Nov 2020 18:48:17
DataPoint Verified.	(b) (4)	11 Aug 2020 18:34:52
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
	Julia Klopfer (b) (4)	05 Aug 2020 20:04:37
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:24:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). DataPoint Verified.	(b) (4), (b) (6)	15 Aug 2020 00:07:42
	(b) (4), (b) (6)	11 Aug 2020 18:34:52
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing at time of first injection' (Site from System).	Bruce Bausk (b) (4)	11 Aug 2020 00:11:52
	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 20:04:37
User entered 'UN UNK 2010'	Julia Klopfer (b) (4)	05 Aug 2020 20:04:37
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:24:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered '0'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:04:37

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:24:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:04:37

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:24:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:04:37

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:24:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:04:37

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:24:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Aug 2020 20:04:37

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 20:04:37

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 20:04:37

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:24:53

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FLUTICASONE PROPIONATE;SALMETEROL XINAFOATE, PRODUCTSYNONYM: ADVAIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 20:25:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 20:25:03
Data point term sent to Coder	System	05 Aug 2020 20:23:55
User entered 'Advair diskus'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:23:29

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:24:53

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:23:29

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:24:53

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'Asthma'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:23:29

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:24:53

[Dose per administration](#)

Audit	User	Time (GMT)
User opened query 'The dose was 250/50mcg from 2010 to 31Aug20, new entry is added for dose change to 500/50mcg from 01Sep20. Please change this to previous dose 250/50.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:18:14
DataPoint Un-verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User entered '500/50' reason for change: Data Entry Error	Monica Feeley (b) (4)	05 Oct 2020 16:40:08
User closed query 'Per source con-med log the dose is marked as 500/50mcg please confirm.' (Site from CRA). DataPoint Verified.	Monica Feeley (b) (4)	05 Oct 2020 16:40:08
Query 'Per source con-med log the dose is marked as 500/50mcg please confirm.' answered with 'medication dose was updated after 1st visit and second entry was added to con med log for new 500/50 mcg dose' (Site from CRA).	(b) (4), (b) (6)	25 Sep 2020 20:28:46
User opened query 'Per source con-med log the dose is marked as 500/50mcg please confirm.' (Site from CRA).	(b) (4), (b) (6)	25 Sep 2020 20:28:43
User entered '250/50' reason for change: Data Entry Error	Julia Klopfer (b) (4)	23 Sep 2020 22:06:55
DataPoint Un-verified.	(b) (4)	
User entered '500/50' reason for change: Data Entry Error	Julia Klopfer (b) (4)	02 Sep 2020 22:51:00
DataPoint Verified.	(b) (4), (b) (6)	02 Sep 2020 14:30:10
User entered '250/50'	Julia Klopfer (b) (4)	02 Sep 2020 14:30:10
	(b) (4)	
	Julia Klopfer (b) (4)	11 Aug 2020 18:34:52
	(b) (4), (b) (6)	
	Julia Klopfer (b) (4)	05 Aug 2020 20:23:29
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:24:53

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:40:47
DataPoint Un-verified.	Julia Klopfer (b) (4)	02 Sep 2020 14:30:10
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4)	02 Sep 2020 14:30:10
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'Other (OTHER)'	Julia Klopfer (b) (4)	05 Aug 2020 20:23:29
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:24:53

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:40:48
DataPoint Un-verified.	Julia Klopfer (b) (4)	02 Sep 2020 14:30:10
User entered empty; reason for change Data Entry Error	Julia Klopfer (b) (4)	02 Sep 2020 14:30:10
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:09:07
User closed query 'Please confirm unit is mlg or mcg?' (Site from CRA).	(b) (4), (b) (6)	26 Aug 2020 15:09:06
Query 'Please confirm unit is mlg or mcg?' answered with 'MCG' (Site from CRA).	Xhoi Mitre (b) (4)	18 Aug 2020 21:11:19
User entered 'MCG' reason for change: Data Entry Error	Xhoi Mitre (b) (4)	18 Aug 2020 21:11:14
User opened query 'Please confirm unit is mlg or mcg?' (Site from CRA).	(b) (4), (b) (6)	11 Aug 2020 18:45:58
DataPoint Un-verified.	(b) (4), (b) (6)	11 Aug 2020 18:45:12
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'mlg'	Julia Klopfer (b) (4)	05 Aug 2020 20:23:29

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:24:53

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'twice daily (BID)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:23:29

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:24:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:23:29

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:24:53

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:23:29

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:24:53

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:23:29

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:24:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). DataPoint Verified.	(b) (4), (b) (6)	15 Aug 2020 00:07:46
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing at time of first injection' (Site from System).	Bruce Bausk (b) (4)	11 Aug 2020 00:12:16
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 20:23:29
User entered 'UN UNK 2010'	Julia Klopfer (b) (4)	05 Aug 2020 20:23:29

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:24:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered '0'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:23:29

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:24:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:40:36
User entered 'No (N)' reason for change: New Information	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 22:54:31
User entered 'Yes (Y)' reason for change: Data Entry Error	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 22:51:00
DataPoint Un-verified.	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 14:30:10
User entered 'No (N)' reason for change: New Information	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 14:30:10
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:23:29

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:24:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:40:33
User entered '31 Aug 2020' reason for change: New Information	Julia Klopfer (b) (4)	02 Sep 2020 22:54:31
User entered empty; reason for change Data Entry Error	Julia Klopfer (b) (4)	02 Sep 2020 22:51:00
DataPoint Un-verified.	Julia Klopfer (b) (4)	02 Sep 2020 14:30:10
User entered '31 Aug 2020' reason for change: New Information	Julia Klopfer (b) (4)	02 Sep 2020 14:30:10
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4)	05 Aug 2020 20:23:29

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:24:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:23:29

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:24:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Aug 2020 20:23:29

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 20:23:29

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 20:23:29

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:24:53

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: VENTOLIN [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 20:28:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 20:28:10
Data point term sent to Coder	System	05 Aug 2020 20:26:03
User entered 'Ventolin'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:26:01

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:24:53

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:26:01

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:24:53

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'Asthma'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:26:01

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:24:53

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered '2'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:26:01

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:24:53

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'puff (PUFF)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:26:01

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:24:53

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:26:01

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:24:53

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'as needed (PRN)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:26:01

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:24:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:26:01

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:24:53

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:26:01

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:24:53

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:26:01

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:24:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). DataPoint Verified.	(b) (4), (b) (6)	15 Aug 2020 00:07:51
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing at time of first injection' (Site from System).	Bruce Bausk (b) (4)	11 Aug 2020 00:12:24
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 20:26:01
User entered 'UN UNK 2010'	Julia Klopfer (b) (4)	05 Aug 2020 20:26:01

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:24:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered '0'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:26:01

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:24:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:26:01

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:24:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:26:01

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:24:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:26:01

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:24:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 20:26:01

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 20:26:01

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 20:26:01

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:24:53

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 21:32:59
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 21:32:59
Data point term sent to Coder	System	05 Aug 2020 20:28:23
User entered 'Amoxicillin'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:27:30

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:24:53

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:27:30

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:24:53

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:10:19
User closed query 'Please check if this needs to be listed on Medical history' (Site from CRA).	(b) (4), (b) (6)	26 Aug 2020 15:09:52
User closed query 'Please confirm if indication is correct since the medication is an antibiotic and will be prescription only.' (Site from CRA).	(b) (4), (b) (6)	26 Aug 2020 15:09:35
Query 'Please check if this needs to be listed on Medical history' answered with 'does not need to be listed' (Site from CRA).	Xhoi Mitre (b) (4)	18 Aug 2020 21:10:15
Query 'Please confirm if indication is correct since the medication is an antibiotic and will be prescription only.' answered with 'indication correct' (Site from CRA).	Xhoi Mitre (b) (4)	18 Aug 2020 21:10:03
User opened query 'Please check if this needs to be listed on Medical history' (Site from CRA).	(b) (4), (b) (6)	11 Aug 2020 18:55:37
User opened query 'Please confirm if indication is correct since the medication is an antibiotic and will be prescription only.' (Site from CRA).	(b) (4), (b) (6)	11 Aug 2020 18:49:36
DataPoint Un-verified.	(b) (4), (b) (6)	11 Aug 2020 18:48:47
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'Dental prophylaxis'	Julia Klopfer (b) (4)	05 Aug 2020 20:27:30

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:24:53

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Source con-med log mentions dose as 2000mg, please check and confirm' (Site from CRA).	(b) (4), (b) (6)	25 Sep 2020 20:29:27
DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 20:29:26
Query 'Source con-med log mentions dose as 2000mg, please check and confirm' answered with 'updated' (Site from CRA).	Julia Klopfer (b) (4)	23 Sep 2020 22:07:28
User entered '2000' reason for change: Data Entry Error	Julia Klopfer (b) (4)	23 Sep 2020 22:07:22
User opened query 'Source con-med log mentions dose as 2000mg, please check and confirm' (Site from CRA).	(b) (4), (b) (6)	23 Sep 2020 18:33:47
DataPoint Un-verified.	(b) (4), (b) (6)	26 Aug 2020 15:10:31
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:10:20
User closed query 'Source con-med log mentions dose as 2000 mg, please check and confirm' (Site from CRA).	(b) (4), (b) (6)	26 Aug 2020 15:10:15
Query 'Source con-med log mentions dose as 2000 mg, please check and confirm' answered with 'confirmed ' (Site from CRA).	Xhoi Mitre (b) (4)	18 Aug 2020 21:10:45
User opened query 'Source con-med log mentions dose as 2000 mg, please check and confirm' (Site from CRA).	(b) (4), (b) (6)	11 Aug 2020 18:47:57
DataPoint Un-verified.	(b) (4), (b) (6)	11 Aug 2020 18:47:13
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered '200'	Julia Klopfer (b) (4)	05 Aug 2020 20:27:30

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:24:53

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Aug 2020 15:10:22
DataPoint Un-verified.	Xhoi Mitre (b) (4)	18 Aug 2020 21:10:47
User entered 'mg (mg)' reason for change: Data Entry Error	Xhoi Mitre (b) (4)	18 Aug 2020 21:10:47
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'ug (ug)'	Julia Klopfer (b) (4)	05 Aug 2020 20:27:30

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:24:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:27:30

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:24:53

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'as needed (PRN)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:27:30

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:24:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:27:30

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:24:53

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'Oral (ORAL)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:27:30

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:24:53

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:27:30

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:24:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). DataPoint Verified.	(b) (4), (b) (6)	15 Aug 2020 00:07:59
	(b) (4), (b) (6)	11 Aug 2020 18:34:52
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing at time of first injection' (Site from System).	Bruce Bausk (b) (4)	11 Aug 2020 00:12:56
	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 20:27:30
User entered 'UN UNK 2011'	Julia Klopfer (b) (4)	05 Aug 2020 20:27:30
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:24:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered '0'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:27:30

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:24:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:27:30

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:24:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:27:30

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:24:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:27:30

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:24:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 20:27:30

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 20:27:30

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 20:27:30

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:24:53

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 14:17:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 14:17:11
Data point term sent to Coder Coding entries removed.	System Jessica Cauley (b) (4) (b) (4)	06 Oct 2020 14:16:24 06 Oct 2020 14:15:35
User closed query 'Ibuprofen- please check if spelling is correct.' (Site from CRA).	(b) (4), (b) (6)	26 Aug 2020 15:14:39
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:32:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:32:44
Query 'Ibuprofen- please check if spelling is correct.' answered with 'corrected' (Site from CRA).	Xhoi Mitre (b) (4) (b) (4)	18 Aug 2020 21:12:07
Data point term sent to Coder Coding entries removed.	System Xhoi Mitre (b) (4) (b) (4)	18 Aug 2020 21:11:57 18 Aug 2020 21:11:49
User entered 'ibuprofen' reason for change: Data Entry Error	Xhoi Mitre (b) (4) (b) (4)	18 Aug 2020 21:11:49
User opened query 'Ibuprofen- please check if spelling is correct.' (Site from CRA).	(b) (4), (b) (6)	11 Aug 2020 18:57:45
DataPoint Un-verified.	(b) (4), (b) (6)	11 Aug 2020 18:57:23
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:24:53

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Aug 2020 20:45:07
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Aug 2020 20:45:07
Data point term sent to Coder	System	05 Aug 2020 20:28:24
User entered 'Ibuprofin'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:28:13

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:24:53

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:28:13

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:24:53

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update the indication to reflect the location and type of ARTHRITIS(e.g. reumathoid, osteo). Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 13:22:10
Query 'Per DM CLR: Please update the indication to reflect the location and type of ARTHRITIS(e.g. reumathoid, osteo). Please reconcile with the AE and Med History eCRFs as appropriate. ' answered with 'joint osteoarthritis' (Site from DM). DataPoint Un-verified.	Jessica Cauley (b) (4)	06 Oct 2020 14:15:43
User entered 'osteoARTHRITIS' reason for change: Data Entry Error	Jessica Cauley (b) (4)	06 Oct 2020 14:15:35
User opened query 'Per DM CLR: Please update the indication to reflect the location and type of ARTHRITIS(e.g. reumathoid, osteo). Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	25 Sep 2020 04:45:47
User closed query 'Please check and confirm if this needs to go on medical history' (Site from CRA). Query 'Please check and confirm if this needs to go on medical history' answered with 'yes added to medical history ' (Site from CRA). User opened query 'Please check and confirm if this needs to go on medical history' (Site from CRA). DataPoint Un-verified.	Xhoi Mitre (b) (4)	18 Aug 2020 21:12:24
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:57:13
User entered 'Arthritis'	Julia Klopfer (b) (4)	05 Aug 2020 20:28:13

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:24:53

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered '600'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:28:13

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:24:53

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'mg (mg)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:28:13

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:24:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:28:13

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:24:53

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'as needed (PRN)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:28:13

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:24:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:28:13

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:24:53

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'Oral (ORAL)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:28:13

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:24:53

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:28:13

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:24:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). DataPoint Verified.	(b) (4), (b) (6)	15 Aug 2020 00:08:04
	(b) (4), (b) (6)	11 Aug 2020 18:34:52
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing at time of first injection' (Site from System).	Bruce Bausk (b) (4)	11 Aug 2020 00:13:17
	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 20:28:13
User entered 'UN UNK 2011'	Julia Klopfer (b) (4)	05 Aug 2020 20:28:13
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:24:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered '0'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:28:13

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:24:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:28:13

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:24:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:28:13

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:24:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:28:13

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:24:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 20:28:13

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 20:28:13

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 20:28:13

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:24:53

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
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)	05 Aug 2020 20:31:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 20:31:12
Data point term sent to Coder	System	05 Aug 2020 20:29:27
User entered 'Multivitamin'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:28:58

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:24:53

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:28:58

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:24:53

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'General Health'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:28:58

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:24:53

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered '1'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:28:58

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:24:53

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'tablet (TABLET)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:28:58

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:24:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:28:58

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:24:53

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'once daily (QD)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:28:58

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:24:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:28:58

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:24:53

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'Oral (ORAL)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:28:58

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:24:53

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:28:58

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:24:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). DataPoint Verified.	(b) (4), (b) (6)	15 Aug 2020 00:08:07
	(b) (4), (b) (6)	11 Aug 2020 18:34:52
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing at time of first injection' (Site from System).	Bruce Bausk (b) (4)	11 Aug 2020 00:13:30
	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 20:28:58
User entered 'UN UNK 2015'	Julia Klopfer (b) (4)	05 Aug 2020 20:28:58
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:24:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered '0'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:28:58

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:24:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:28:58

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:24:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:28:58

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:24:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:28:58

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:24:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 20:28:58

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 20:28:58

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 20:28:58

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:24:53

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 20:48:00
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 20:48:00
Data point term sent to Coder	System	05 Aug 2020 20:37:43
User entered 'Vitamin C'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:37:07

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:24:53

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:37:07

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:24:53

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'General Health'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:37:07

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:24:53

[Dose per administration](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review the dose and unit recorded as this is not the standard dosage for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'This is the standard for international units' (Site from DM).	Monica Feeley (b) (4) (b) (4)	10 Nov 2020 21:06:04
User opened query 'Per DM CLR: Please review the dose and unit recorded as this is not the standard dosage for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6) (b) (4)	22 Oct 2020 08:53:52
User closed query 'Per DM CLR: Please review the dosage as this is not the expected dosage for this medication. Please review and either correct dosage or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6) (b) (4)	20 Oct 2020 05:05:50
Query 'Per DM CLR: Please review the dosage as this is not the expected dosage for this medication. Please review and either correct dosage or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate.' answered with 'expected dosage' (Site from DM).	Monica Feeley (b) (4) (b) (4)	05 Oct 2020 16:37:19
User opened query 'Per DM CLR: Please review the dosage as this is not the expected dosage for this medication. Please review and either correct dosage or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6) (b) (4)	25 Sep 2020 04:46:30
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	11 Aug 2020 18:34:52
User entered '10,000'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:37:07

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:24:53

[Dose unit](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication. Please correct the unit as appropriate.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 05:05:52
Query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication. Please correct the unit as appropriate.' answered with 'expected unit' (Site from DM).	Monica Feeley (b) (4)	05 Oct 2020 16:37:11
User opened query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication. Please correct the unit as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 04:46:42
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:44:00
DataPoint Un-verified.	Xhoi Mitre (b) (4)	18 Aug 2020 21:06:19
User entered 'IU (IU)' reason for change: Data Entry Error	Xhoi Mitre (b) (4)	18 Aug 2020 21:06:19
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'ug (ug)'	Julia Klopfer (b) (4)	05 Aug 2020 20:37:07

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:24:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:37:07

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:24:53

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'twice daily (BID)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:37:07

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:24:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:37:07

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:24:53

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'Oral (ORAL)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:37:07

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:24:53

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:37:07

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:24:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). DataPoint Verified.	(b) (4), (b) (6)	15 Aug 2020 00:08:14
	(b) (4), (b) (6)	11 Aug 2020 18:34:52
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing at time of first injection' (Site from System).	Bruce Bausk (b) (4)	11 Aug 2020 00:13:39
	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 20:37:07
User entered 'UN UNK 2015'	Julia Klopfer (b) (4)	05 Aug 2020 20:37:07
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:24:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered '0'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:37:07

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:24:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:37:07

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:24:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:37:07

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:24:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:37:07

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:24:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Aug 2020 20:37:07

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 20:37:07

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 20:37:07

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:24:53

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: ASCORBIC ACID;BROMELAINS;CALCIUM PANTOTHENATE;CURCUMA LONGA RHIZOME;CYSTEINE;ENZYMES NOS;MAGNESIUM OXIDE;RUSCUS ACULEATUS RHIZOME;RUSCUS ACULEATUS ROOT, PRODUCTSYNONYM: CURCUMAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 22:59:04
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 22:59:04
Data point term sent to Coder	System	05 Aug 2020 20:38:45
User entered 'Curcumax'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:38:20

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:24:53

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:38:20

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:24:53

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'General Health'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:38:20

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:24:53

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered '1'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:38:20

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:24:53

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'tablet (TABLET)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:38:20

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:24:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:38:20

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:24:53

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'once daily (QD)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:38:20

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:24:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:38:20

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:24:53

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'Oral (ORAL)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:38:20

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:24:53

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:38:20

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:24:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). DataPoint Verified.	(b) (4), (b) (6)	15 Aug 2020 00:08:18
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing at time of first injection' (Site from System).	Bruce Bausk (b) (4)	11 Aug 2020 00:13:53
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 20:38:20
User entered 'UN UNK 2010'	Julia Klopfer (b) (4)	05 Aug 2020 20:38:20

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:24:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered '0'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:38:20

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:24:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:38:20

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:24:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:38:20

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:24:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:38:20

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:24:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 20:38:20

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 20:38:20

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 20:38:20

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:24:53

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 15:39:40
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 15:39:40
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:44:36
Data point term sent to Coder	System	18 Sep 2020 12:58:36
User closed query 'RQCoding: Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	System	18 Sep 2020 12:58:17
Query 'RQCoding: Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' answered with 'updated' (Site from System).	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 12:58:17
User entered 'MYOCALM PLUS (Calcium, magnesium, passionflower flower 5.5:1 Extract, valerian root extract, hops cone 7.5:1 Extract, lemon balm Leaf 4:1 Extract)' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	18 Sep 2020 12:58:03
User opened query 'RQCoding: Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	Coder Import (b) (4) (b) (4)	10 Sep 2020 13:01:35
User closed query 'Please confirm if this is Myocom or Myocalm' (Site from CRA).	(b) (4), (b) (6)	26 Aug 2020 15:14:09
Data point term sent to Coder	System	18 Aug 2020 21:13:59
User closed query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' (Site from System).	System	18 Aug 2020 21:13:56

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:24:53

[Name of Medication](#)

Audit	User	Time (GMT)
Query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' answered with 'myocalm plus' (Site from System).	Xhoi Mitre (b) (4)	18 Aug 2020 21:13:56
Query 'Please confirm if this is Myocom or Myocalm' answered with 'myocalm plus ' (Site from CRA).	Xhoi Mitre (b) (4)	18 Aug 2020 21:13:46
User entered 'MYOCALM PLUS' reason for change: Data Entry Error	Xhoi Mitre (b) (4)	18 Aug 2020 21:13:28
User opened query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' (Site from System).	Coder Import (b) (4)	17 Aug 2020 12:39:04
User opened query 'Please confirm if this is Myocom or Myocalm' (Site from CRA).	(b) (4), (b) (6)	11 Aug 2020 19:01:01
DataPoint Un-verified.	(b) (4), (b) (6)	11 Aug 2020 19:00:30
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
Data point term sent to Coder	System	05 Aug 2020 20:40:46
User entered 'Myocom Plus'	Julia Klopfer (b) (4)	05 Aug 2020 20:40:21
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:24:53

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:40:21

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:24:53

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'General Health'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:40:21

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:24:53

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered '1'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:40:21

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:24:53

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'tablet (TABLET)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:40:21

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:24:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:40:21

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:24:53

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'once daily (QD)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:40:21

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:24:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:40:21

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:24:53

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'Oral (ORAL)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:40:21

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:24:53

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:40:21

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:24:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). DataPoint Verified.	(b) (4), (b) (6)	15 Aug 2020 00:08:22
	(b) (4), (b) (6)	11 Aug 2020 18:34:52
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing at time of first injection' (Site from System).	Bruce Bausk (b) (4)	11 Aug 2020 00:14:01
	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 20:40:21
User entered 'UN UNK 2010'	Julia Klopfer (b) (4)	05 Aug 2020 20:40:21
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:24:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered '0'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:40:21

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:24:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:40:21

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:24:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:40:21

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:24:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:40:21

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:24:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 20:40:21

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 20:40:21

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 20:40:21

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:24:53

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: PROBIOTICS NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 08:53:28
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 08:53:28
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
Data point term sent to Coder	System	05 Aug 2020 20:41:49
User entered 'Probiotic Ultrafloraspectrum'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:41:15

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:24:53

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:41:15

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:24:53

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'General health'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:41:15

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:24:53

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered '1'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:41:15

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:24:53

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'capsule (CAPSULE)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:41:15

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:24:53

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:41:15

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:24:53

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'once daily (QD)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:41:15

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:24:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:41:15

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:24:53

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'Oral (ORAL)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:41:15

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:24:53

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:41:15

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:24:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). DataPoint Verified.	(b) (4), (b) (6)	15 Aug 2020 00:08:27
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing at time of first injection' (Site from System).	Bruce Bausk (b) (4)	11 Aug 2020 00:14:15
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 20:41:15
User entered 'UN UNK 2010'	Julia Klopfer (b) (4)	05 Aug 2020 20:41:15

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:24:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered '0'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:41:15

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:24:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:41:15

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:24:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered empty.	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:41:15

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:24:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 18:34:52
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:41:15

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:24:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 20:41:15

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 20:41:15

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 20:41:15

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:24:53

[Name of Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 07:07:44
Query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication. ' answered with 'no' (Site from DM).	Monica Feeley (b) (4)	10 Nov 2020 21:06:18
User opened query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 08:49:01
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:51:09
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FLUTICASONE PROPIONATE;SALMETEROL XINAFOATE, PRODUCTSYNONYM: ADVAIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 22:54:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 22:54:54
Data point term sent to Coder	System	02 Sep 2020 22:54:21
User entered 'Advair Diskus'	Julia Klopfer (b) (4)	02 Sep 2020 22:53:37

v6.020 DTW (1102)

2218 of 2438

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:24:53

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:51:12
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 22:53:37

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:24:53

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:51:10
User entered 'Asthma'	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 22:53:37

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:24:53

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:51:16
User entered '500/50'	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 22:53:37

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:24:53

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:51:14
User entered 'ug (ug)'	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 22:53:37

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:24:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:51:20
User entered empty.	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 22:53:37

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:24:53

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:51:18
User entered 'twice daily (BID)'	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 22:53:37

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:24:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:51:24
User entered empty.	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 22:53:37

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:24:53

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:51:22
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 22:53:37

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:24:53

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:51:26
User entered empty.	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 22:53:37

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:51:28
User entered '01 Sep 2020'	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 22:53:37

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:24:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:51:30
User entered '0'	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 22:53:37

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:24:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:51:31
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 22:53:37

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:24:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:51:33
User entered empty.	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 22:53:37

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:24:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:51:35
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	02 Sep 2020 22:53:37

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:24:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	02 Sep 2020 22:53:37

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 22:53:37

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 22:53:37

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:24:53

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
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: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 07:16:54
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 07:16:54
Data point term sent to Coder	System	23 Sep 2020 22:02:52
User entered 'ibuprofen'	Julia Klopfer (b) (4) (b) (4)	23 Sep 2020 22:02:38

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:24:53

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 22:02:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Sep 2020 22:02:45
User entered 'No (N)' reason for change: Data Entry Error	Julia Klopfer (b) (4)	23 Sep 2020 22:02:45
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 22:02:38
User entered empty.	Julia Klopfer (b) (4)	23 Sep 2020 22:02:38

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:24:53

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User entered 'dental procedure pain management'	Julia Klopfer (b) (4) (b) (4)	23 Sep 2020 22:02:38

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:24:53

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User entered '600'	Julia Klopfer (b) (4) (b) (4)	23 Sep 2020 22:02:38

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:24:53

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User entered 'mg (mg)'	Julia Klopfer (b) (4) (b) (4)	23 Sep 2020 22:02:38

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:24:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User entered empty.	Julia Klopfer (b) (4) (b) (4)	23 Sep 2020 22:02:38

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:24:53

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User entered 'as needed (PRN)'	Julia Klopfer (b) (4) (b) (4)	23 Sep 2020 22:02:38

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:24:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User entered empty.	Julia Klopfer (b) (4) (b) (4)	23 Sep 2020 22:02:38

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:24:53

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User entered 'Oral (ORAL)'	Julia Klopfer (b) (4) (b) (4)	23 Sep 2020 22:02:38

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:24:53

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User entered empty.	Julia Klopfer (b) (4) (b) (4)	23 Sep 2020 22:02:38

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User entered '22 Sep 2020'	Julia Klopfer (b) (4) (b) (4)	23 Sep 2020 22:02:38

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:24:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User entered '0'	Julia Klopfer (b) (4) (b) (4)	23 Sep 2020 22:02:38

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:24:53

[Ongoing?](#)

Audit	User	Time (GMT)
User opened query 'Please check with subject if this is ongoing as she already taking same medication and same dose from 2011 for osteoarthritis. Please check and edit' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 18:20:33
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	23 Sep 2020 22:02:38
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:24:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User entered empty.	Julia Klopfer (b) (4) (b) (4)	23 Sep 2020 22:02:38

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:24:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	23 Sep 2020 22:02:38

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:24:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 22:02:38

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 22:02:38

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 22:02:38

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:24:53

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
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)	23 Sep 2020 22:05:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 22:05:44
Data point term sent to Coder	System	23 Sep 2020 22:04:54
User entered 'influenza vaccine'	Julia Klopfer (b) (4) (b) (4)	23 Sep 2020 22:04:14

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:24:53

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 22:04:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Sep 2020 22:04:20
User entered 'Yes (Y)' reason for change: Data Entry Error	Julia Klopfer (b) (4)	23 Sep 2020 22:04:20
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 22:04:14
User entered empty.	Julia Klopfer (b) (4)	23 Sep 2020 22:04:14

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:24:53

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User entered 'prophylaxis'	Julia Klopfer (b) (4) (b) (4)	23 Sep 2020 22:04:14

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:24:53

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User entered '1'	Julia Klopfer (b) (4) (b) (4)	23 Sep 2020 22:04:14

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:24:53

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User entered 'Other (OTHER)'	Julia Klopfer (b) (4) (b) (4)	23 Sep 2020 22:04:14

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:24:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User entered 'injection'	Julia Klopfer (b) (4) (b) (4)	23 Sep 2020 22:04:14

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:24:53

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User entered 'once (ONCE)'	Julia Klopfer (b) (4) (b) (4)	23 Sep 2020 22:04:14

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:24:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User entered empty.	Julia Klopfer (b) (4) (b) (4)	23 Sep 2020 22:04:14

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:24:53

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User entered 'Intramuscular (INTRAMUSCULAR)'	Julia Klopfer (b) (4) (b) (4)	23 Sep 2020 22:04:14

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:24:53

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User entered empty.	Julia Klopfer (b) (4) (b) (4)	23 Sep 2020 22:04:14

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User entered '17 Sep 2020'	Julia Klopfer (b) (4) (b) (4)	23 Sep 2020 22:04:14

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:24:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User entered '0'	Julia Klopfer (b) (4) (b) (4)	23 Sep 2020 22:04:14

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:24:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	23 Sep 2020 22:04:14

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:24:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User entered '17 Sep 2020'	Julia Klopfer (b) (4) (b) (4)	23 Sep 2020 22:04:14

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:24:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	23 Sep 2020 22:04:14

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:24:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 22:04:14

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 22:04:14

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 22:04:14

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:24:53

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 15:03:14
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 15:03:14
Data point term sent to Coder	System	06 Oct 2020 14:20:41
User entered 'Amoxicillin'	Jessica Cauley (b) (4) (b) (4)	06 Oct 2020 14:20:05

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:24:53

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User entered 'Yes (Y)'	Jessica Cauley (b) (4) (b) (4)	06 Oct 2020 14:20:05

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:24:53

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User entered 'prophylaxis dental procedures'	Jessica Cauley (b) (4) (b) (4)	06 Oct 2020 14:20:05

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:24:53

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User entered '2000'	Jessica Cauley (b) (4) (b) (4)	06 Oct 2020 14:20:05

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:24:53

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User entered 'mg (mg)'	Jessica Cauley (b) (4) (b) (4)	06 Oct 2020 14:20:05

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:24:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User entered empty.	Jessica Cauley (b) (4) (b) (4)	06 Oct 2020 14:20:05

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:24:53

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User entered 'once (ONCE)'	Jessica Cauley (b) (4)	06 Oct 2020 14:20:05
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:24:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User entered empty.	Jessica Cauley (b) (4) (b) (4)	06 Oct 2020 14:20:05

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:24:53

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User entered 'Oral (ORAL)'	Jessica Cauley (b) (4) (b) (4)	06 Oct 2020 14:20:05

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:24:53

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User entered empty.	Jessica Cauley (b) (4) (b) (4)	06 Oct 2020 14:20:05

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User entered '09 Sep 2020'	Jessica Cauley (b) (4) (b) (4)	06 Oct 2020 14:20:05

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:24:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User entered '0'	Jessica Cauley (b) (4)	06 Oct 2020 14:20:05
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:24:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User entered 'No (N)'	Jessica Cauley (b) (4)	06 Oct 2020 14:20:05
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:24:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User entered '09 Sep 2020'	Jessica Cauley (b) (4)	06 Oct 2020 14:20:05
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:24:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:42:48
User entered 'No (N)'	Jessica Cauley (b) (4)	06 Oct 2020 14:20:05
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:24:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 14:20:05

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 14:20:05

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 14:20:05

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:24:53

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:56:02
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 04:06:42
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 04:06:42
Data point term sent to Coder	System	24 Oct 2020 13:34:02
User entered 'Metoprolol'	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:33:19

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:24:53

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:56:02
User entered 'No (N)'	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:33:19

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:24:53

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:56:02
User entered 'A-fib'	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:33:19

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:24:53

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:56:02
User entered '5'	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:33:19

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:24:53

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:56:02
User entered 'mg (mg)'	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:33:19

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:24:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:56:02
User entered empty.	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:33:19

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:24:53

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:56:02
User entered 'once (ONCE)'	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:33:19

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:24:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:56:02
User entered empty.	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:33:19

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:24:53

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:56:02
User entered 'Intravenous (INTRAVENOUS)'	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:33:19

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:24:53

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:56:02
User entered empty.	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:33:19

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:56:02
User entered '23 Oct 2020'	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:33:19

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:24:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:56:02
User entered '0'	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:33:19

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:24:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:56:02
User entered 'No (N)'	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:33:19

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:24:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:56:02
User entered '23 Oct 2020'	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:33:19

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:24:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:56:02
User entered 'No (N)'	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:33:19

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:24:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Oct 2020 13:33:19

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Oct 2020 13:33:19

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Oct 2020 13:33:19

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:24:53

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:56:02
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)	24 Oct 2020 13:59:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Oct 2020 13:59:36
Data point term sent to Coder	System	24 Oct 2020 13:58:08
User entered 'Zofran'	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:57:26

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:24:53

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:56:02
User entered 'No (N)'	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:57:26

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:24:53

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:56:02
User entered 'nausea'	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:57:26

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:24:53

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:56:02
User entered '4'	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:57:26

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:24:53

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:56:02
User entered 'mg (mg)'	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:57:26

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:24:53

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:56:02
User entered empty.	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:57:26

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:24:53

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:56:02
User entered 'once (ONCE)'	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:57:26

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:24:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:56:02
User entered empty.	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:57:26

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:24:53

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:56:02
User entered 'Oral (ORAL)'	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:57:26

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:24:53

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:56:02
User entered empty.	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:57:26

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:56:02
User entered '23 Oct 2020'	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:57:26

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:24:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:56:02
User entered '0'	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:57:26

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:24:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:56:02
User entered 'No (N)'	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:57:26

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:24:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:56:02
User entered '23 Oct 2020'	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:57:26

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:24:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 21:56:02
User entered 'No (N)'	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:57:26

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:24:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Oct 2020 13:57:26

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Oct 2020 13:57:26

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Oct 2020 13:57:26

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 09:24:53

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:25:23
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)	20 Nov 2020 16:51:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	20 Nov 2020 16:51:01
Data point term sent to Coder	System	20 Nov 2020 16:03:58
User entered 'Acetaminophen'	Monica Feeley (b) (4)	20 Nov 2020 16:03:22
	(b) (4)	

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 09:24:53

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:25:21
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 16:03:22

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 09:24:53

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Since this was given during hospitalization, include the reference in the Indication, e.g: Pain for XX during hospitalization for GERD.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 18:24:43
User entered 'mild pain'	Monica Feeley (b) (4)	20 Nov 2020 16:03:22

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 09:24:53

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:23:14
User entered '650'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 16:03:22

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 09:24:53

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:23:13
User entered 'mg (mg)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 16:03:22

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 09:24:53

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:23:11
User entered empty.	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 16:03:22

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 09:24:53

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:23:09
User entered 'other (OTHER)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 16:03:22

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 09:24:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:23:07
User entered 'every 6 hours'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 16:03:22

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 09:24:53

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:23:05
User entered 'Oral (ORAL)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 16:03:22

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 09:24:53

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:23:03
User entered empty.	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 16:03:22

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 09:24:53

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:23:01
User entered '24 Oct 2020'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 16:03:22

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 09:24:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:22:55
User entered '0'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 16:03:22

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 09:24:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:22:53
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 16:03:22

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 09:24:53

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:22:52
User entered '24 Oct 2020'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 16:03:22

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 09:24:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:22:50
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 16:03:22

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 09:24:53

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 16:03:22

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 16:03:22

US3432016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 26 Nov 2020 09:24:53

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Nov 2020 16:03:22

US3432016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:24:53

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:37:20
User closed query 'Per CDM : Were any concomitant procedures performed is 'No', however the details were provided in Logline#11 and 12 in the concomitant procedures eCRF page. Kindly update the data as appropriate else clarify in query response.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 05:31:25
Query 'Per CDM : Were any concomitant procedures performed is 'No', however the details were provided in Logline#11 and 12 in the concomitant procedures eCRF page. Kindly update the data as appropriate else clarify in query response.' answered with 'data updated ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 21:12:52
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 21:12:41
DataPoint Un-verified.	(b) (4), (b) (6)	23 Sep 2020 18:53:43
DataPoint Verified.	(b) (4), (b) (6)	23 Sep 2020 18:53:12
User opened query 'Per CDM : Were any concomitant procedures performed is 'No', however the details were provided in Logline#11 and 12 in the concomitant procedures eCRF page. Kindly update the data as appropriate else clarify in query response.' (Site from DM).	(b) (4), (b) (6)	20 Sep 2020 12:19:55
User closed query 'Per eCRF guidelines (pg 37) please record procedures only after first dose of study vaccine. Please delete all these details' (Site from CRA).	(b) (4), (b) (6)	14 Sep 2020 12:00:53
Query 'Per eCRF guidelines (pg 37) please record procedures only after first dose of study vaccine. Please delete all these details' answered with 'deleted' (Site from CRA).	Xhoi Mitre (b) (4) (b) (4)	18 Aug 2020 21:04:26
User entered 'No (N)' reason for change: Data Entry Error	Xhoi Mitre (b) (4) (b) (4)	18 Aug 2020 21:04:15
User opened query 'Per eCRF guidelines (pg 37) please record procedures only after first dose of study vaccine. Please delete all these details' (Site from CRA).	(b) (4), (b) (6)	11 Aug 2020 19:06:24
DataPoint Un-verified.	(b) (4), (b) (6)	11 Aug 2020 19:05:25

US3432016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:24:53

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Aug 2020 19:03:47
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	05 Aug 2020 20:43:48

US3432016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 26 Nov 2020 09:24:53

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:20:34
User entered '24 Aug 2020'	Phoebe Cunningham (b) (4)	26 Aug 2020 20:04:30

US3432016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 26 Nov 2020 09:24:53

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:20:34
User entered 'CT Scan'	Phoebe Cunningham (b) (4)	26 Aug 2020 20:04:30

US3432016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 26 Nov 2020 09:24:53

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:20:34
User entered 'Diagnostic (DIAGNOSTIC)'	Phoebe Cunningham (b) (4)	26 Aug 2020 20:04:30

US3432016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 26 Nov 2020 09:24:53

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:20:34
User entered empty.	Phoebe Cunningham	26 Aug 2020 20:04:30
	(b) (4)	

US3432016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 26 Nov 2020 09:24:53

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:20:34
User entered '9 Sep 2020'	Phoebe Cunningham (b) (4)	16 Sep 2020 22:25:18

US3432016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 26 Nov 2020 09:24:53

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:20:34
User entered 'Dental implant'	Phoebe Cunningham (b) (4)	16 Sep 2020 22:25:18

US3432016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 26 Nov 2020 09:24:53

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:20:34
User entered 'Other (OTHER)'	Phoebe Cunningham	16 Sep 2020 22:25:18
	(b) (4)	

US3432016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 26 Nov 2020 09:24:53

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:20:34
User entered 'dental care'	Phoebe Cunningham (b) (4)	16 Sep 2020 22:25:18

US3432016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 26 Nov 2020 09:24:53

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:20:34
User entered '22 Sep 2020'	Julia Klopfer (b) (4) (b) (4)	23 Sep 2020 21:59:35

US3432016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 26 Nov 2020 09:24:53

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:20:34
User entered 'dental implant'	Julia Klopfer (b) (4) (b) (4)	23 Sep 2020 21:59:35

US3432016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 26 Nov 2020 09:24:53

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Indication = Medical History, however, there is no corresponding medical condition recorded for this procedure in the MedHistory eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 13:20:21
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:20:34
Query 'Per DM CLR: Indication = Medical History, however, there is no corresponding medical condition recorded for this procedure in the MedHistory eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify.' answered with 'updated' (Site from DM).	Monica Feeley (b) (4)	05 Oct 2020 18:11:48
User entered 'Other (OTHER)' reason for change: Data Entry Error	Monica Feeley (b) (4)	05 Oct 2020 18:11:43
User opened query 'Per DM CLR: Indication = Medical History, however, there is no corresponding medical condition recorded for this procedure in the MedHistory eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 08:20:35
User entered 'Medical History (MH)'	Julia Klopfer (b) (4)	23 Sep 2020 21:59:35

US3432016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 26 Nov 2020 09:24:53

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:20:34
User entered 'dental care' reason for change: Data Entry Error	Monica Feeley (b) (4)	05 Oct 2020 18:11:43
User entered empty.	Julia Klopfer (b) (4)	23 Sep 2020 21:59:35

US3432016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 26 Nov 2020 09:24:53

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:20:34
User entered '27 Aug 2020'	Monica Feeley (b) (4)	05 Oct 2020 16:44:42
	(b) (4)	

US3432016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 26 Nov 2020 09:24:53

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:20:34
User entered 'Breathing test'	Monica Feeley (b) (4)	05 Oct 2020 16:44:42
	(b) (4)	

US3432016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 26 Nov 2020 09:24:53

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:20:34
User entered 'Diagnostic (DIAGNOSTIC)'	Monica Feeley (b) (4) (b) (4)	05 Oct 2020 16:44:42

US3432016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 26 Nov 2020 09:24:53

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:20:34
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Oct 2020 16:44:42

US3432016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (15)

Generated On: 26 Nov 2020 09:24:53

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:20:34
User entered '15 Sep 2020'	Monica Feeley (b) (4) (b) (4)	05 Oct 2020 16:48:02

US3432016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (15)

Generated On: 26 Nov 2020 09:24:53

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:20:34
User entered 'mammogram'	Monica Feeley (b) (4)	05 Oct 2020 16:48:02
	(b) (4)	

US3432016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (15)

Generated On: 26 Nov 2020 09:24:53

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:20:34
User entered 'Diagnostic (DIAGNOSTIC)'	Monica Feeley (b) (4) (b) (4)	05 Oct 2020 16:48:02

US3432016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (15)

Generated On: 26 Nov 2020 09:24:53

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:20:34
User entered empty.	Monica Feeley (b) (4)	05 Oct 2020 16:48:02
	(b) (4)	

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'USA-US078-2020-MRNA-1273-P301000008'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'Yes (Y)'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'No (N)'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'No (N)'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'Yes (Y)'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'No (N)'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'No (N)'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'No (N)'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'Lindsey'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'Baden'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'MA'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:33:35
User entered 'US'	System	26 Oct 2020 20:49:37

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	24 Nov 2020 02:53:43
User entered '3'	System	11 Nov 2020 14:26:12
User entered '2'	System	06 Nov 2020 19:33:54
User entered '1'	System	26 Oct 2020 20:49:37

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'USA-US078-2020-MRNA-1273-P301000008'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'Yes (Y)'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'No (N)'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'No (N)'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'Yes (Y)'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'No (N)'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'No (N)'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'No (N)'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'Lindsey'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'Baden'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'MA'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:33:35
User entered 'US'	System	26 Oct 2020 20:49:37

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	24 Nov 2020 02:53:43
User entered '3'	System	11 Nov 2020 14:26:12
User entered '2'	System	06 Nov 2020 19:33:54
User entered '1'	System	26 Oct 2020 20:49:37

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:24:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
User entered '26/Oct/2020 16:49'	System	26 Oct 2020 20:49:37

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:24:53

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)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:33:35
User entered '1'	(b) (4), (b) (6)	26 Oct 2020 20:49:37

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'USA-US078-2020-MRNA-1273-P301000008'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'Yes (Y)'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'No (N)'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'No (N)'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'Yes (Y)'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'No (N)'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'No (N)'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'No (N)'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'Lindsey'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'Baden'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'MA'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:33:35
User entered 'US'	System	26 Oct 2020 20:49:37

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	24 Nov 2020 02:53:43
User entered '3'	System	11 Nov 2020 14:26:12
User entered '2'	System	06 Nov 2020 19:33:54
User entered '1'	System	26 Oct 2020 20:49:37

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:24:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
User entered '06/Nov/2020 19:33'	System	06 Nov 2020 19:33:54

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:24:53

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 14:25:38
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
User entered '1'	(b) (4), (b) (6)	06 Nov 2020 19:33:54

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'USA-US078-2020-MRNA-1273-P301000008'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'Yes (Y)'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'No (N)'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'No (N)'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'Yes (Y)'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'No (N)'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'No (N)'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'No (N)'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'Lindsey'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'Baden'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'MA'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:33:35
User entered 'US'	System	26 Oct 2020 20:49:37

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	24 Nov 2020 02:53:43
User entered '3'	System	11 Nov 2020 14:26:12
User entered '2'	System	06 Nov 2020 19:33:54
User entered '1'	System	26 Oct 2020 20:49:37

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:24:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:39:01
User entered '11/Nov/2020 14:26'	System	11 Nov 2020 14:26:12

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:24:53

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)	24 Nov 2020 02:53:35
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:39:01
User entered '1'	(b) (4), (b) (6)	11 Nov 2020 14:26:12

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'USA-US078-2020-MRNA-1273-P301000008'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'Yes (Y)'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'No (N)'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'No (N)'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'Yes (Y)'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'No (N)'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'No (N)'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'No (N)'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'Lindsey'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'Baden'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 20:49:23
User entered 'MA'	System	26 Oct 2020 20:48:42

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 20:41:28
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:33:35
User entered 'US'	System	26 Oct 2020 20:49:37

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 26 Nov 2020 09:24:53

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	24 Nov 2020 02:53:43
User entered '3'	System	11 Nov 2020 14:26:12
User entered '2'	System	06 Nov 2020 19:33:54
User entered '1'	System	26 Oct 2020 20:49:37

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:24:53

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '23/Nov/2020 21:53'	System	24 Nov 2020 02:53:43

US3432016

Folder: SAE USA-US078-2020-MRNA-1273-P301000008

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:24:53

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)	24 Nov 2020 02:53:43