

US3322353 (Prod: DM Clinical Research - Texas Center For Drug Development - ERN - PPDS)

Generated By: (b) (6)

Generated On: 26 Nov 2020 10:56:38

All time stamps listed in this document are displayed in GMT

US3322353

Form: Participant Creation

Generated On: 26 Nov 2020 10:56:38

[Participant ID](#)

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:56:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:38

Date of Birth (MMM yyyy)	(b) (6) 1947
Age	73
Age Units	YEARS
Age (Derived)	73
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:56:38

Date of Informed Consent (<i>dd MMM yyyy</i>)	15 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:56:38

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:56:38

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:56:38

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

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:56:38

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

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:56:38

Condition	BENIGN PROSTATIC HYPERPLASIA
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:56:38

Condition	ERECTILE DYSFUNCTION
Start date (dd MMM yyyy)	UN UNK 1984
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1984
Start Year (derived)	1984
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:56:38

Condition	HIATAL HERNIA SURGERY
Start date (dd MMM yyyy)	UN UNK 1995
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="checkbox"/> No <input checked="" type="radio"/>
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

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:56:38

Condition	INDIRECT INGUINAL HERNIA SURGERY
Start date (dd MMM yyyy)	UN UNK 1997
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1997
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1997
Start Year (derived)	1997
Stop Month and Year (derived)	JAN 1997
Stop Year (derived)	1997

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:56:38

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

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:56:38

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

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:56:38

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

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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:56:38

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

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Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:56:38

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

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Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:56:38

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

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Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:56:38

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

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Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:56:38

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

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	15 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	14:50 (24 HR)
Vital Signs Date and Time (derived)	15 SEP 2020 14:50
Height (<i>xxx.x</i>)	75 in
Weight (<i>xxx.x</i>)	200 lb
BMI (<i>xxx.x</i>)	25.05056 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:56:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:38

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify

CONTRACTOR INTERACTING
WITH 6-10 PEOPLE /DAY.
WORKS >3 DAYS /WK

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	True
Specify	GROCERY SHOPPING 1/ WEEK . GOES TO GYM 3 TIMES / WEEK . LIVES WITH HIS WIFE WHO HAS OCCUPATION REQUIRING CLOSE OR FREQUENT CONTACT WITH PEOPLE (REALTOR)

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:56:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:56:38

What was the date of randomization? (dd MMM yyyy) 15 SEP 2020

What was the participant's randomization number? 190610

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:56:38

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:38

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 SEP 2020
Time of assessment (00:00-23:59)	15:01 (24 HR)
Vital Signs Date and Time (derived)	15 SEP 2020 15:01
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:38

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 SEP 2020
Time of assessment (00:00-23:59)	17:18 (24 HR)
Vital Signs Date and Time (derived)	15 SEP 2020 17:18
Temperature (xxx.x)	96.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	155 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:56:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 SEP 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:56:38

Was study treatment given?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, reason not given	Participant declined due to Adverse Event <input type="radio"/>
	Physician withheld dose due to Adverse Event <input type="radio"/>
	Death <input type="radio"/>
	Lost To Follow-Up <input type="radio"/>
	Physician Decision <input type="radio"/>
	Pregnancy <input type="radio"/>
	Protocol Deviation <input type="radio"/>
	Study Terminated by Sponsor <input type="radio"/>
	Withdrawal of Consent by Participant <input type="radio"/>
	Confirmed COVID-19 <input type="radio"/>
	Other <input type="radio"/>
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)	15 SEP 2020
What was the treatment time? (00:00-23:59)	16:33 (24 HR)
Treatment Date and Time (derived)	15 SEP 2020 16:33
Which arm was used to give treatment?	Left Arm <input checked="" type="radio"/>
	Right Arm <input type="radio"/>
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:56:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	15 SEP 2020
Collection time (<i>00:00-23:59</i>)	16:01 (24 HR)
Collection date and time (derived)	15 SEP 2020 16:01

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:56:38

Collection date (<i>dd MMM yyyy</i>)			15 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:54	15 SEP 2020 15:54
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:56:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 17:12

PC Open Date & Time

15 SEP 2020 16:53

PC Close Date & Time

15 SEP 2020 19:23

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 96.5 °F

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

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

PC Time Stamp	16 SEP 2020 09:33
PC Open Date & Time	15 SEP 2020 20:18
PC Close Date & Time	16 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

16 SEP 2020 15:29

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.3 °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

17 SEP 2020 17:18

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

18 SEP 2020 15:06

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 14:51

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

20 SEP 2020 13:30

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.4 °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

21 SEP 2020 13:20

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 17:14

PC Open Date & Time

15 SEP 2020 16:53

PC Close Date & Time

15 SEP 2020 19:23

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 09:34

PC Open Date & Time

15 SEP 2020 20:18

PC Close Date & Time

16 SEP 2020 11:59

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 15:31

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 17:18

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 15:07

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 14:51

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 SEP 2020 13:30

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 13:21

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

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

No ☒

Yes ☐

PC Time stamp	15 SEP 2020 17:15
PC Open Date & Time	15 SEP 2020 16:53
PC Close Date & Time	15 SEP 2020 19:23

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 09:35
PC Open Date & Time	15 SEP 2020 20:18
PC Close Date & Time	16 SEP 2020 11:59

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:38

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 15:31
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:38

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 17:19
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:38

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 15:07
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:38

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 14:52
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:38

		Yes <input type="checkbox"/>
PC Time stamp	20 SEP 2020 13:31	
PC Open Date & Time	20 SEP 2020 12:00	
PC Close Date & Time	21 SEP 2020 11:59	

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:38

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 13:21
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3322353

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:38

Was Contact Attempted?

Yes ☒

No ☐

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

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322353

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322353

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:38

Was Contact Attempted?

Yes ☒

No ☐

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

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322353

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322353

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:38

Was Contact Attempted?

Yes ☒

No ☐

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

6 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322353

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322353

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:56:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:38

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 OCT 2020
Time of assessment (00:00-23:59)	13:09 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 13:09
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:38

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 OCT 2020
Time of assessment (00:00-23:59)	14:40 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 14:40
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	54 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3322353

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:56:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 OCT 2020

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

US3322353

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:56:38

Was study treatment given?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, reason not given	Participant declined due to Adverse Event <input type="radio"/>
	Physician withheld dose due to Adverse Event <input type="radio"/>
	Death <input type="radio"/>
	Lost To Follow-Up <input type="radio"/>
	Physician Decision <input type="radio"/>
	Pregnancy <input type="radio"/>
	Protocol Deviation <input type="radio"/>
	Study Terminated by Sponsor <input type="radio"/>
	Withdrawal of Consent by Participant <input type="radio"/>
	Confirmed COVID-19 <input type="radio"/>
	Other <input type="radio"/>
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)	13 OCT 2020
What was the treatment time? (00:00-23:59)	14:03 (24 HR)
Treatment Date and Time (derived)	13 OCT 2020 14:03
Which arm was used to give treatment?	Left Arm <input checked="" type="radio"/>
	Right Arm <input type="radio"/>
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

US3322353

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:56:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	13 OCT 2020
Collection time (<i>00:00-23:59</i>)	13:55 (24 HR)
Collection date and time (derived)	13 OCT 2020 13:55

US3322353

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:56:38

Collection date (dd MMM yyyy)			13 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:50	13 OCT 2020 13:50
Nasopharyngeal Swab 2	No		

US3322353

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

13 OCT 2020 14:40

PC Open Date & Time

13 OCT 2020 14:23

PC Close Date & Time

13 OCT 2020 16:53

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.2 °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	13 OCT 2020 18:47
PC Open Date & Time	13 OCT 2020 17:48
PC Close Date & Time	14 OCT 2020 11:59

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

14 OCT 2020 13:02

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 OCT 2020 14:16

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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

16 OCT 2020 16:18

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

17 OCT 2020 17:49

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 OCT 2020 16:36

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

19 OCT 2020 13:39

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 OCT 2020 14:41

PC Open Date & Time

13 OCT 2020 14:23

PC Close Date & Time

13 OCT 2020 16:53

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 OCT 2020 18:45

PC Open Date & Time

13 OCT 2020 17:48

PC Close Date & Time

14 OCT 2020 11:59

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 OCT 2020 13:02

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 OCT 2020 14:16

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 OCT 2020 16:18

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 OCT 2020 17:49

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 OCT 2020 16:36

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 OCT 2020 13:39

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

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

No ☒

Yes ☐

PC Time stamp	13 OCT 2020 14:41
PC Open Date & Time	13 OCT 2020 14:23
PC Close Date & Time	13 OCT 2020 16:53

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

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

No ☒

Yes ☐

PC Time stamp	13 OCT 2020 18:46
PC Open Date & Time	13 OCT 2020 17:48
PC Close Date & Time	14 OCT 2020 11:59

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:38

Yes <input type="checkbox"/>	
PC Time stamp	14 OCT 2020 13:03
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:38

Yes <input type="checkbox"/>	
PC Time stamp	15 OCT 2020 14:16
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:38

Yes <input type="checkbox"/>	
PC Time stamp	16 OCT 2020 16:18
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:38

Yes <input type="checkbox"/>	
PC Time stamp	17 OCT 2020 17:50
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:38

Yes <input type="checkbox"/>	
PC Time stamp	18 OCT 2020 16:36
PC Open Date & Time	18 OCT 2020 12:00
PC Close Date & Time	19 OCT 2020 11:59

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:38

Yes <input type="checkbox"/>	
PC Time stamp	19 OCT 2020 13:39
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3322353

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:38

Was Contact Attempted?

Yes ☒

No ☐

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

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322353

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322353

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:38

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

US3322353

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322353

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:38

Was Contact Attempted?

Yes ☒

No ☐

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

4 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322353

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322353

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:56:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3322353

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	10 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	12:05 (24 HR)
Vital Signs Date and Time (derived)	10 NOV 2020 12:05
Temperature (<i>xxx.x</i>)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	78 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3322353

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:56:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 NOV 2020

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

US3322353

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:56:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	10 NOV 2020
Collection time (<i>00:00-23:59</i>)	13:07 (24 HR)
Collection date and time (derived)	10 NOV 2020 13:07

US3322353

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322353

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 NOV 2020 12:47:18

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 NOV 2020 00:01
Patient Cloud Close Date & Time	16 NOV 2020 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 12:44:46
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

[Patient Cloud Open Date & Time](#)

03 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2020 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

[Patient Cloud Open Date & Time](#)

17 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2020 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

[Patient Cloud Open Date & Time](#)

31 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

[Patient Cloud Open Date & Time](#)

14 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

[Patient Cloud Open Date & Time](#)

21 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 138

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

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

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

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

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

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

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

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 152

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

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

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

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

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

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

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

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 159

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

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

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

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

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

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

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

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 173

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

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

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

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

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

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

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

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

[Patient Cloud Open Date & Time](#)

18 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 194

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

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

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 MAR 2021 00:01
Patient Cloud Close Date & Time	29 MAR 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

[Patient Cloud Open Date & Time](#)

15 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

[Patient Cloud Open Date & Time](#)

29 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 MAY 2021 00:01
Patient Cloud Close Date & Time	17 MAY 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 JUL 2021 00:01
Patient Cloud Close Date & Time	26 JUL 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 390

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

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

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	07 OCT 2021 00:01
Patient Cloud Close Date & Time	11 OCT 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

Patient Cloud Open Date & Time	21 OCT 2021 00:01
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Patient Cloud Close Date & Time	25 OCT 2021 23:59
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US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 NOV 2021 00:01
Patient Cloud Close Date & Time	29 NOV 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

[Patient Cloud Open Date & Time](#)

02 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 467

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

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

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

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

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

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

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

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	30 DEC 2021 00:01
Patient Cloud Close Date & Time	03 JAN 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 JAN 2022 00:01
Patient Cloud Close Date & Time	31 JAN 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 509

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

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

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

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

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

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

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

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	03 FEB 2022 00:01
Patient Cloud Close Date & Time	07 FEB 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

Date and time of submission	
Patient Cloud Open Date & Time	10 FEB 2022 00:01
Patient Cloud Close Date & Time	14 FEB 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

Date and time of submission	
Patient Cloud Open Date & Time	17 FEB 2022 00:01
Patient Cloud Close Date & Time	21 FEB 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 544

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

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

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

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

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

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

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

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

[Patient Cloud Open Date & Time](#)

10 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 551

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

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

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

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

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

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

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

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 MAR 2022 00:01
Patient Cloud Close Date & Time	21 MAR 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 558

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

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

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

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

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

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

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

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

[Patient Cloud Open Date & Time](#)

14 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 586

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

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

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

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

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

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

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

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

[Patient Cloud Open Date & Time](#)

21 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 593

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

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

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

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

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

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

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

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 642

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

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

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

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

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

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

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

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 663

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

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

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

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

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

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

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

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 JUL 2022 00:01
Patient Cloud Close Date & Time	18 JUL 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 JUL 2022 00:01
Patient Cloud Close Date & Time	25 JUL 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 698

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

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

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

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

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

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

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

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 705

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

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

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

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

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

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

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

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

Patient Cloud Open Date & Time	25 AUG 2022 00:01
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Patient Cloud Close Date & Time	29 AUG 2022 23:59
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US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 733

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

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

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

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

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

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

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

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 SEP 2022 00:01
Patient Cloud Close Date & Time	26 SEP 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 OCT 2022 00:01
Patient Cloud Close Date & Time	17 OCT 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT	DAY 775
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

Patient Cloud Open Date & Time	27 OCT 2022 00:01
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Patient Cloud Close Date & Time	31 OCT 2022 23:59
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US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

[Patient Cloud Open Date & Time](#)

03 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2022 23:59

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

Patient Cloud Open Date & Time	10 NOV 2022 00:01
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Patient Cloud Close Date & Time	14 NOV 2022 23:59
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US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

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

[Patient Cloud Open Date & Time](#)

17 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2022 23:59

US3322353

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:38

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322353

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:38

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3322353

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 10:56:38

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

US3322353

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 10:56:38

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3322353

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:56:38

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3322353

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:38

AEID	USA-US060-2020-MRNA-1273-P30 1000007
Adverse event	PROSTATE ADENOCARCINOMA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	16 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

v6.020 DTW (1102) 341 of 2057

US3322353

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:38

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT CALLED OUR SITE ON 27 OCT 2020 TO LET US KNOW THAT ON FRIDAY 23 OCT 2020 HE FOUND OUT THAT HE HAS PROSTATE CANCER. BIOPSY OF PROSTATE WAS ON 16 OCT 2020 THUS START DATE WAS CHANGED.
Serious Adverse Event Derived (CSA Programming Field Only)	1

US3322353

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:38

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

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:38

AEID	
Adverse event	GASTROESOPHAGEAL REFLUX DISEASE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	03 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:38

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

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:56:38

AEID

Adverse event

LOWER URINARY TRACT
SYMPTOMS

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)

29 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

02 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

v6.020 DTW (1102)

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:56:38

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

US3322353

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:56:38

AEID	
Adverse event	COLONIC DIVERTICULOSIS
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	25 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:56:38

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

US3322353

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:56:38

AEID	
Adverse event	BLADDER DIVERTICULA
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	25 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:56:38

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:56:38

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:38

Name of Medication	TESTOSTERONE CYPIONATE
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	ERECTILE DYSFUNCTION
Dose per administration	750
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input checked="" type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:38

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 1987	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:38

Name of Medication	FINASTERIDE
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	BENIGN PROSTATIC HYPERPLASIA
Dose per administration	5
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:38

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2014
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:38

Name of Medication	ALFUZOSIN
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	BENIGN PROSTATIC HYPERPLASIA
Dose per administration	10
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:38

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2014
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:38

Name of Medication	TRIAMTERENE
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	PEDAL EDEMA
Dose per administration	25
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:38

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:38

Name of Medication	MULTI VITAMIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	SUPPLEMENTS
Dose per administration	1
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input checked="" type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:38

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:38

Name of Medication	FOLIC ACID
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	SUPPLEMENTS
Dose per administration	400
Dose unit	mg <input type="radio"/> ug <input checked="" type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:38

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 1985
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:38

Name of Medication	METAMUCIL
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	IRRITABLE BOWEL SYNDROME
Dose per administration	11000
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:38

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:38

Name of Medication	IMODIUM
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	IRRITABLE BOWEL SYNDROME
Dose per administration	1/2
Dose unit	mg <input type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input checked="" type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input checked="" type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:38

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:56:38

Name of Medication	DESMOPRESSIN
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	URINARY INCONTINENCE
Dose per administration	0.2
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input checked="" type="checkbox"/>
If frequency is Other, specify	
ONE TABLET 2-3 TIMES A WEEK	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/> Intramuscular <input type="checkbox"/>

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:56:38

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <input type="text"/>		
<hr/>		
Start date (dd MMM yyyy)		6 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <input type="text"/>		
<hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)		<input type="text"/>
Interval Dosage Unit Number (derived)		<input type="text"/>
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:56:38

Name of Medication	OMEPRAZOLE
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	OMEPRAZOLE
Dose per administration	40
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input checked="" type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:56:38

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		04 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:38

Name of Medication	CIPROFLOXACIN
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	LOWER URINARY TRACT SYMPTOMS
Dose per administration	500
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input type="checkbox"/> twice daily <input checked="" type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:38

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 02 OCT 2020		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:56:38

Name of Medication	METRONIDAZOLE
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	LOWER URINARY TRACT SYMPTOMS
Dose per administration	500
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input checked="" type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:56:38

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		29 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 02 OCT 2020		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:56:38

Name of Medication	SILDENAFIL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	PULMONARY HYPERTENSION
Dose per administration	20
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input checked="" type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:56:38

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		19 NOV 2019
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:56:38

Name of Medication	SILDENAFIL
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	ERECTILE DYSFUNCTION
Dose per administration	100
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input checked="" type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/> Intramuscular <input type="radio"/>

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:56:38

	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <hr/>		
Start date (dd MMM yyyy)	UN	UNK 1998
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy)	16 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
<hr/>		
Separate Dosage Number (derived)	<hr/>	
Interval Dosage Unit Number (derived)	<hr/>	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:56:38

Name of Medication	GENTAMICIN SULFATE
Prophylaxis	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Indication	LOWER URINARY TRACT SYMPTOMS
Dose per administration	80
Dose unit	mg <input checked="" type="checkbox"/> ug <input type="checkbox"/> mL <input type="checkbox"/> g <input type="checkbox"/> IU <input type="checkbox"/> tablet <input type="checkbox"/> capsule <input type="checkbox"/> puff <input type="checkbox"/> Other <input type="checkbox"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="checkbox"/> twice daily <input type="checkbox"/> three times daily <input type="checkbox"/> four times daily <input type="checkbox"/> every other day <input type="checkbox"/> every week <input type="checkbox"/> every month <input type="checkbox"/> as needed <input type="checkbox"/> once <input checked="" type="checkbox"/> unknown <input type="checkbox"/> other <input type="checkbox"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="checkbox"/> Topical <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Transdermal <input type="checkbox"/> Intraocular <input type="checkbox"/>

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:56:38

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		29 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 29 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3322353

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:56:38

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3322353

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 10:56:38

Procedure/Surgery date (<i>dd MMM yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
16 OCT 2020	PROSTATE BIOPSY	Diagnostic	
25 SEP 2020	PROSTATE MAGNETIC RESONANCE IMAGING WITH OR WITH OUT CONTRAST	Diagnostic	

US3322353

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 10:56:38

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

US3322353

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 10:56:38

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:38

SAEID	USA-US060-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:56:38

SAEID	USA-US060-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	29/OCT/2020 13:46
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:56:38

SAEID	USA-US060-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	16/NOV/2020 09:21
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3322353 (Prod: DM Clinical Research - Texas Center For Drug Development - ERN - PPDS)

US3322353

Form: Participant Creation

Generated On: 26 Nov 2020 10:56:38

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3322353'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	15 Sep 2020 20:14:15

US3322353

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:56:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:42:27

US3322353

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:56:38

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

Audit	User	Time (GMT)
User entered '15 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	15 Sep 2020 20:14:17

US3322353

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:56:38

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:42:27

US3322353

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 10:56:38

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	15 Sep 2020 21:42:27

US3322353

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:38

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

Audit	User	Time (GMT)
User entered (b) (6) 1947'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	15 Sep 2020 20:14:18

US3322353

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:38

[Age](#)

Audit	User	Time (GMT)
User entered '73'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:43:28

US3322353

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:38

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	15 Sep 2020 21:43:28

US3322353

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:38

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '73'	System	15 Sep 2020 21:41:55

US3322353

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:38

Sex

Audit	User	Time (GMT)
User entered 'Male (M)'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:43:28

US3322353

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:38

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:43:28

US3322353

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:38

White

Audit	User	Time (GMT)
User entered '1'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:43:28

US3322353

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:38

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:43:28

US3322353

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:38

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:43:28

US3322353

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:38

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:43:28

US3322353

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:38

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:43:28

US3322353

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:38

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:43:28

US3322353

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:38

If race is Other, specify

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:43:28

US3322353

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:38

Unknown

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:43:28

US3322353

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 10:56:38

Not reported

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:43:28

US3322353

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:56:38

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Sep 2020'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:41:55

US3322353

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:56:38

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

Audit	User	Time (GMT)
User entered 'Sep 2020'	System	15 Sep 2020 21:41:55

US3322353

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:56:38

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

Audit	User	Time (GMT)
User entered '2020'	System	15 Sep 2020 21:41:55

US3322353

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:56:38

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 3 (3)'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:41:55

US3322353

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:56:38

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:41:55

US3322353

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:56:38

If No, indicate reason for screen fail

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:41:55

US3322353

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:56:38

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:41:55

US3322353

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:56:38

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:41:55

US3322353

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:56:38

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	15 Sep 2020 20:14:17

US3322353

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 10:56:38

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Sep 2020 21:42:00

US3322353

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 10:56:38

Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:42:00

US3322353

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 10:56:38

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:43:37

US3322353

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:56:38

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal spastic and hypermotility disorders, PT: Irritable bowel syndrome, LLT: Irritable bowel syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 21:45:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 21:45:51
Data point term sent to Coder	System	15 Sep 2020 21:44:30
User entered 'Irritable Bowel syndrome'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:43:55

US3322353

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:56:38

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

Audit	User	Time (GMT)
User entered 'UN UNK 2015'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:43:55

US3322353

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:56:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:43:55

US3322353

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:56:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:43:55

US3322353

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:56:38

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

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:43:55

US3322353

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:56:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:43:55

US3322353

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:56:38

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	15 Sep 2020 21:43:55

US3322353

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:56:38

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

Audit	User	Time (GMT)
User entered '2015'	System	15 Sep 2020 21:43:55

US3322353

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:56:38

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

Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 21:43:55

US3322353

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 10:56:38

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

Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 21:43:55

US3322353

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:56:38

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal vascular conditions, HLT: Haemorrhoids and gastrointestinal varices (excl oesophageal), PT: Haemorrhoids, LLT: Internal hemorrhoids - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 21:45:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 21:45:51
Data point term sent to Coder	System	15 Sep 2020 21:44:32
User entered 'internal Hemorrhoids'	Frances Saubon (b) (4)	15 Sep 2020 21:44:05

US3322353

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:56:38

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

Audit	User	Time (GMT)
User entered 'UN UNK 2016'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:44:05

US3322353

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:56:38

Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:44:05

US3322353

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:56:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:44:05

US3322353

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:56:38

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

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:44:05

US3322353

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:56:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:44:05

US3322353

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:56:38

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

Audit	User	Time (GMT)
User entered 'Jan 2016'	System	15 Sep 2020 21:44:05

US3322353

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:56:38

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

Audit	User	Time (GMT)
User entered '2016'	System	15 Sep 2020 21:44:05

US3322353

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:56:38

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

Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 21:44:05

US3322353

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 10:56:38

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

Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 21:44:05

US3322353

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:56:38

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hyperplasia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 21:45:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 21:45:51
Data point term sent to Coder	System	15 Sep 2020 21:44:32
User entered 'benign prostatic hyperplasia'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:44:24

US3322353

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:56:38

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

Audit	User	Time (GMT)
User entered 'UN UNK 1990'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:44:24

US3322353

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:56:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:44:24

US3322353

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:56:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:44:24

US3322353

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:56:38

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

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:44:24

US3322353

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:56:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:44:24

US3322353

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:56:38

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

Audit	User	Time (GMT)
User entered 'Jan 1990'	System	15 Sep 2020 21:44:24

US3322353

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:56:38

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

Audit	User	Time (GMT)
User entered '1990'	System	15 Sep 2020 21:44:24

US3322353

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:56:38

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

Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 21:44:24

US3322353

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 10:56:38

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

Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 21:44:24

US3322353

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:56:38

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Sexual function and fertility disorders, HLT: Erection and ejaculation conditions and disorders, PT: Erectile dysfunction, LLT: Erectile dysfunction - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 21:46:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 21:46:50
Data point term sent to Coder	System	15 Sep 2020 21:45:35
User entered 'Erectile Dysfunction'	Frances Saubon (b) (4)	15 Sep 2020 21:44:36
	(b) (4)	

US3322353

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:56:38

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

Audit	User	Time (GMT)
User entered 'UN UNK 1984'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:44:36

US3322353

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:56:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:44:36

US3322353

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:56:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:44:36

US3322353

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:56:38

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

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:44:36

US3322353

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:56:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:44:36

US3322353

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:56:38

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1984'	System	15 Sep 2020 21:44:36

US3322353

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:56:38

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1984'	System	15 Sep 2020 21:44:36

US3322353

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:56:38

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 21:44:36

US3322353

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 10:56:38

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 21:44:36

US3322353

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:56:38

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Respiratory tract therapeutic procedures, HLT: Diaphragmatic therapeutic procedures, PT: Hernia hiatus repair, LLT: Hiatal hernia repair - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 21:46:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 21:46:50
Data point term sent to Coder	System	15 Sep 2020 21:45:35
User entered 'Hiatal Hernia surgery'	Frances Saubon (b) (4)	15 Sep 2020 21:45:03
	(b) (4)	

US3322353

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:56:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 1995'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:45:03

US3322353

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:56:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:45:03

US3322353

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:56:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:45:03

US3322353

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:56:38

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'UN UNK 1995'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:45:03

US3322353

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:56:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:45:03

US3322353

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:56:38

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1995'	System	15 Sep 2020 21:45:03

US3322353

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:56:38

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1995'	System	15 Sep 2020 21:45:03

US3322353

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:56:38

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1995'	System	15 Sep 2020 21:45:03

US3322353

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 10:56:38

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1995'	System	15 Sep 2020 21:45:03

US3322353

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:56:38

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Hernia repairs, PT: Inguinal hernia repair, LLT: Inguinal hernia repair - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 06:13:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 06:13:53
Data point term sent to Coder	System	15 Sep 2020 21:46:36
User entered 'indirect inguinal Hernia surgery'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:45:56

US3322353

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:56:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 1997'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:45:56

US3322353

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:56:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:45:56

US3322353

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:56:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:45:56

US3322353

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:56:38

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'UN UNK 1997'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:45:56

US3322353

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:56:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:45:56

US3322353

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:56:38

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1997'	System	15 Sep 2020 21:45:56

US3322353

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:56:38

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1997'	System	15 Sep 2020 21:45:56

US3322353

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:56:38

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1997'	System	15 Sep 2020 21:45:56

US3322353

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 10:56:38

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1997'	System	15 Sep 2020 21:45:56

US3322353

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:56:38

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLG: Gastrointestinal therapeutic procedures, HLT: Anorectal therapeutic procedures, PT: Haemorrhoid operation, LLT: Hemorrhoid ligation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 06:12:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 06:12:50
Data point term sent to Coder	System	15 Sep 2020 21:46:36
User entered 'internal hemorrhoid ligation procedure'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:46:13

US3322353

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:56:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 2018'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:46:13

US3322353

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:56:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:46:13

US3322353

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:56:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:46:13

US3322353

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:56:38

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'UN UNK 2018'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:46:13

US3322353

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:56:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:46:13

US3322353

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:56:38

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	15 Sep 2020 21:46:13

US3322353

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:56:38

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2018'	System	15 Sep 2020 21:46:13

US3322353

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:56:38

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	15 Sep 2020 21:46:13

US3322353

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 10:56:38

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2018'	System	15 Sep 2020 21:46:13

US3322353

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:56:38

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLG: Gastrointestinal therapeutic procedures, HLT: Anorectal therapeutic procedures, PT: Haemorrhoid operation, LLT: Hemorrhoid ligation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 06:12:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 06:12:50
Data point term sent to Coder	System	15 Sep 2020 21:46:36
User entered 'internal hemorrhoid ligation procedure'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:46:29

US3322353

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:56:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN UNK 2019'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:46:29

US3322353

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:56:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:46:29

US3322353

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:56:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:46:29

US3322353

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:56:38

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'UN UNK 2019'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:46:29

US3322353

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:56:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:46:29

US3322353

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:56:38

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	15 Sep 2020 21:46:29

US3322353

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:56:38

Start Year (derived)

Audit	User	Time (GMT)
User entered '2019'	System	15 Sep 2020 21:46:29

US3322353

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:56:38

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	15 Sep 2020 21:46:29

US3322353

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 10:56:38

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2019'	System	15 Sep 2020 21:46:29

US3322353

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:56:38

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Disability issues, PT: Hearing aid user, LLT: Hearing aid user - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 21:48:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	15 Sep 2020 21:48:53
Data point term sent to Coder	System	15 Sep 2020 21:47:39
User entered 'Hearing Aids'	Frances Saubon (b) (4)	15 Sep 2020 21:46:43
	(b) (4)	

US3322353

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:56:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'UN Mar 2020'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:46:43

US3322353

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:56:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:46:43

US3322353

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:56:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:46:43

US3322353

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:56:38

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:46:43

US3322353

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:56:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:46:43

US3322353

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:56:38

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Mar 2020'	System	15 Sep 2020 21:46:43

US3322353

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:56:38

Start Year (derived)

Audit	User	Time (GMT)
User entered '2020'	System	15 Sep 2020 21:46:43

US3322353

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:56:38

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 21:46:43

US3322353

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 10:56:38

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 21:46:43

US3322353

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:56:38

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema peripheral, LLT: Pedal edema - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 21:53:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 21:53:04
Data point term sent to Coder	System	30 Oct 2020 21:52:05
User entered 'pedal edema'	Elisa Moralez (b) (4)	30 Oct 2020 21:51:26
	(b) (4)	

US3322353

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:56:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 2020'	Elisa Moralez (b) (4) (b) (4)	30 Oct 2020 21:51:26

US3322353

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:56:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	30 Oct 2020 21:51:26

US3322353

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:56:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	30 Oct 2020 21:51:26

US3322353

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:56:38

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	30 Oct 2020 21:51:26

US3322353

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:56:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	30 Oct 2020 21:51:26

US3322353

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:56:38

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2020'	System	30 Oct 2020 21:51:26

US3322353

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:56:38

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2020'	System	30 Oct 2020 21:51:26

US3322353

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:56:38

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 21:51:26

US3322353

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 10:56:38

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 21:51:26

US3322353

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:56:38

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Urinary incontinence, LLT: Urinary incontinence - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 21:53:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 21:53:04
Data point term sent to Coder	System	30 Oct 2020 21:52:05
User entered 'urinary incontinence'	Elisa Moralez (b) (4) (b) (4)	30 Oct 2020 21:51:49

US3322353

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:56:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 2018'	Elisa Moralez (b) (4) (b) (4)	30 Oct 2020 21:51:49

US3322353

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:56:38

Start date completely unknown

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	30 Oct 2020 21:51:49

US3322353

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:56:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	30 Oct 2020 21:51:49

US3322353

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:56:38

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	30 Oct 2020 21:51:49

US3322353

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:56:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	30 Oct 2020 21:51:49

US3322353

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:56:38

Start Month and Year (derived)

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	30 Oct 2020 21:51:49

US3322353

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:56:38

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2018'	System	30 Oct 2020 21:51:49

US3322353

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:56:38

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 21:51:49

US3322353

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 10:56:38

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 21:51:49

US3322353

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:56:38

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Investigations, HLGT: Cytogenetic investigations, HLT: Cell marker analyses, PT: Prostatic specific antigen increased, LLT: Prostate specific antigen increased - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 23:46:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 23:46:44
Data point term sent to Coder	System	10 Nov 2020 21:16:28
User entered 'elevation of prostate-specific antigen'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:15:28

US3322353

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:56:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 2015'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:15:28

US3322353

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:56:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:15:28

US3322353

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:56:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:15:28

US3322353

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:56:38

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:15:28

US3322353

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:56:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:15:28

US3322353

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:56:38

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	10 Nov 2020 21:15:28

US3322353

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:56:38

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2015'	System	10 Nov 2020 21:15:28

US3322353

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:56:38

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:15:28

US3322353

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 10:56:38

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:15:28

US3322353

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:56:38

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Investigations, HLGT: Reproductive organ and breast investigations (excl hormone analyses), HLT: Reproductive organ and breast histopathology procedures, PT: Biopsy prostate normal, LLT: Prostatic biopsy normal - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 06:07:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 06:07:45
Data point term sent to Coder	System	10 Nov 2020 21:16:27
User entered 'prostatic biopsy for hyperplasia - negative'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:15:46

US3322353

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:56:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 2015'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:15:46

US3322353

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:56:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:15:46

US3322353

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:56:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:15:46

US3322353

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:56:38

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'un UNK 2015'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:15:46

US3322353

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:56:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:15:46

US3322353

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:56:38

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	10 Nov 2020 21:15:46

US3322353

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:56:38

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2015'	System	10 Nov 2020 21:15:46

US3322353

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:56:38

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	10 Nov 2020 21:15:46

US3322353

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 10:56:38

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2015'	System	10 Nov 2020 21:15:46

US3322353

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:56:38

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Pulmonary vascular disorders, HLT: Pulmonary hypertensions, PT: Pulmonary hypertension, LLT: Pulmonary hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 22:47:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 22:47:44
Data point term sent to Coder	System	10 Nov 2020 22:46:33
User entered 'pulmonary hypertension'	(b) (4), (b) (6)	10 Nov 2020 22:46:16

US3322353

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:56:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 2019'	(b) (4), (b) (6)	10 Nov 2020 22:46:16

US3322353

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:56:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 22:46:16

US3322353

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:56:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 22:46:16

US3322353

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:56:38

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 22:46:16

US3322353

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:56:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	10 Nov 2020 22:46:16

US3322353

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:56:38

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	10 Nov 2020 22:46:16

US3322353

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:56:38

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2019'	System	10 Nov 2020 22:46:16

US3322353

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:56:38

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:46:16

US3322353

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 10:56:38

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:46:16

US3322353

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:38

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:47:54

US3322353

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Sep 2020'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:47:54

US3322353

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:38

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User entered '14:50'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:47:54

US3322353

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 14:50'	System	15 Sep 2020 21:47:54

US3322353

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:38

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered '75' in	Frances Saubon (b) (4)	15 Sep 2020 21:47:54
DataPoint set to visible.	(b) (4) System	15 Sep 2020 21:42:00

US3322353

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:38

Weight (xxx.x)

Audit	User	Time (GMT)
User entered '200' lb	Frances Saubon (b) (4)	15 Sep 2020 21:47:54
DataPoint set to visible.	(b) (4) System	15 Sep 2020 21:42:00

US3322353

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:38

BMI (xxx.x)

Audit	User	Time (GMT)
User entered '25.05056'	System	15 Sep 2020 21:47:54
DataPoint set to visible.	System	15 Sep 2020 21:42:00

US3322353

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:38

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	15 Sep 2020 21:47:54
DataPoint set to visible.	System	15 Sep 2020 21:42:00

US3322353

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:38

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:47:54

US3322353

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:38

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:47:54

US3322353

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:38

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:47:54

US3322353

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:47:54

US3322353

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:38

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	15 Sep 2020 21:47:54

US3322353

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:47:54

US3322353

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	15 Sep 2020 21:47:54

US3322353

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:47:54

US3322353

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Sep 2020 21:47:54

US3322353

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:47:54

US3322353

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	15 Sep 2020 21:47:54

US3322353

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:56:38

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:48:00

US3322353

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 10:56:38

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Sep 2020'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:48:00

US3322353

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:38

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:48:40

US3322353

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:38

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:48:40

US3322353

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:38

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:48:40

US3322353

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:38

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:48:40

US3322353

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:38

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:48:40

US3322353

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:38

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:48:40

US3322353

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:38

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:48:40

US3322353

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:38

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:48:40

US3322353

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:38

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:48:40

US3322353

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:38

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:48:40

US3322353

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:38

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:48:40

US3322353

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:38

[Other](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:48:40

US3322353

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:38

[Specify](#)

Audit	User	Time (GMT)
User entered 'contractor interacting with 6-10 people /day. Works >3 days /wk'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:48:40

US3322353

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:38

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:48:40

US3322353

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:38

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:48:40

US3322353

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:38

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:48:40

US3322353

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:38

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:48:40

US3322353

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:38

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:48:40

US3322353

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:38

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:48:40

US3322353

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:38

[Other](#)

Audit	User	Time (GMT)
User entered 'I'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:48:40

US3322353

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 10:56:38

[Specify](#)

Audit	User	Time (GMT)
User entered 'grocery shopping 1/ week . Goes to Gym 3 times / week . Lives with his wife who has occupation requiring close or frequent contact with people (realtor)'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:48:40

US3322353

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:56:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:49:25

US3322353

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:56:38

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Visit 1 Date is not equal to the Visit 1 Treatment Date. Please reconcile or confirm dates.' (Site from System).	System	17 Sep 2020 13:49:44
Query 'Visit 1 Date is not equal to the Visit 1 Treatment Date. Please reconcile or confirm dates.' answered by data change (Site from System).	System	17 Sep 2020 13:49:44
User entered '15 Sep 2020' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:49:44
User opened query 'Visit 1 Date is not equal to the Visit 1 Treatment Date. Please reconcile or confirm dates.' (Site from System).	System	17 Sep 2020 13:49:25
User entered '16 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:49:25

US3322353

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:56:38

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:49:25

US3322353

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 10:56:38

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	17 Sep 2020 13:49:25

US3322353

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:56:38

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'The Randomization Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	17 Sep 2020 13:49:44
Query 'The Randomization Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	17 Sep 2020 13:49:44
User opened query 'The Randomization Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	17 Sep 2020 13:49:25
User entered '15 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	15 Sep 2020 20:44:28

US3322353

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:56:38

What was the participant's randomization number?

Audit	User	Time (GMT)
User entered '190610'	RWS_ENDPOINT ENDPOINT (b) (4) <div></div>	15 Sep 2020 20:44:28

US3322353

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:56:38

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	15 Sep 2020 20:44:28

US3322353

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:56:38

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:50:01

US3322353

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:56:38

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:50:01

US3322353

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:56:38

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:50:01

US3322353

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:56:38

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:50:01

US3322353

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:56:38

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:50:01

US3322353

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 10:56:38

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4)	27 Sep 2020 02:48:15
Amendment Manager: DataPoint set to visible.	(b) (4)	19 Sep 2020 09:17:58
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 09:17:57

US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:56:38

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:12

US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:56:38

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:12

US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:56:38

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:12

US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:56:38

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:12

US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:38

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:12

US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:38

Were vital signs assessed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:12

US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	17 Sep 2020 13:51:22
User entered '15 Sep 2020' reason for change: Data Entry Error	Elisa Morales (b) (4)	17 Sep 2020 13:51:22
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	17 Sep 2020 13:51:12
User entered '16 Sep 2020'	Elisa Morales (b) (4)	17 Sep 2020 13:51:12

US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:38

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	17 Sep 2020 13:51:22
User opened query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	17 Sep 2020 13:51:12
User entered '15:01'	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:12

US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 15:01'	System	17 Sep 2020 13:51:22
User entered '16 Sep 2020 15:01'	System	17 Sep 2020 13:51:12

US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:38

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.7' F	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:12

US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:38

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:12

US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:38

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:12

US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '62'	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:12

US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:38

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	17 Sep 2020 13:51:12

US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '15'	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:12

US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	17 Sep 2020 13:51:12

US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '137'	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:12

US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Sep 2020 13:51:12

US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '89'	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:12

US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Sep 2020 13:51:12

US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:56:38

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:12

US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 10:56:38

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:12

US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:38

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:12

US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User closed query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	17 Sep 2020 13:51:31
User entered 'Yes (Y)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:31
User opened query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	17 Sep 2020 13:51:12
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:12

US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	17 Sep 2020 13:51:31
User entered '15 Sep 2020' reason for change: Data Entry Error	Elisa Moralez (b) (4)	17 Sep 2020 13:51:31
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	17 Sep 2020 13:51:12
User entered '16 Sep 2020'	Elisa Moralez (b) (4)	17 Sep 2020 13:51:12

US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:38

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User entered '17:18'	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:12

US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 17:18'	System	17 Sep 2020 13:51:31
User entered '16 Sep 2020 17:18'	System	17 Sep 2020 13:51:12

US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:38

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	21 Sep 2020 12:50:38
User closed query 'Per CDM: Site response noted; however, please confirm if the PI considers the event to be CS or NCS. Refer to CCGs for more details. Thank you. (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 06:43:32
Query 'Per CDM: Site response noted; however, please confirm if the PI considers the event to be CS or NCS. Refer to CCGs for more details. Thank you. answered with 'NCS' (Site from DM).	Frances Saubon (b) (4) (b) (4)	18 Sep 2020 21:49:42
User opened query 'Per CDM: Site response noted; however, please confirm if the PI considers the event to be CS or NCS. Refer to CCGs for more details. Thank you. (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 17:31:45
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'PER SOURCE' (Site from System).	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:51
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 13:51:12
User entered '96.5' F	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:12

US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:38

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:12

US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:38

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:12

US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '56'	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:12

US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:38

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	17 Sep 2020 13:51:12

US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '15'	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:12

US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	17 Sep 2020 13:51:12

US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '155'	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:12

US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Sep 2020 13:51:12

US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '83'	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:51:12

US3322353

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Sep 2020 13:51:12

US3322353

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:56:38

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:52:23

US3322353

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 10:56:38

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:52:23

US3322353

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:56:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:42:14

US3322353

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:56:38

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:42:14

US3322353

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:56:38

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:42:14

US3322353

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:56:38

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	15 Sep 2020 21:42:14

US3322353

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:56:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'The Treatment Date is not equal toSystem the Visit Date. Please review and reconcile.' (Site from System).		17 Sep 2020 13:49:44
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	17 Sep 2020 13:49:44
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	System	17 Sep 2020 13:49:25
User entered '15 Sep 2020'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:42:14

US3322353

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:56:38

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '16:33'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:42:14

US3322353

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:56:38

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 16:33'	System	15 Sep 2020 21:42:14

US3322353

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:56:38

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Frances Saubon (b) (4) (b) (4)	15 Sep 2020 21:42:14

US3322353

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:56:38

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	15 Sep 2020 21:42:14

US3322353

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 10:56:38

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	15 Sep 2020 21:42:14

US3322353

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:56:38

Was the sample collected?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:52:40

US3322353

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:56:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:52:40

US3322353

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:56:38

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '16:01'	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:52:40

US3322353

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:56:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 16:01'	System	17 Sep 2020 13:52:40

US3322353

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:56:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '15 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:52:50

US3322353

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:56:38

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:52:50

US3322353

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:56:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:52:50

US3322353

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:56:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '15:54'	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:52:50

US3322353

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:56:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 15:54'	System	17 Sep 2020 13:52:50

US3322353

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:56:38

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:52:50

US3322353

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:56:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:52:50

US3322353

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:56:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:52:50

US3322353

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:56:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 13:52:50

US3322353

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:56:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 13:52:54

US3322353

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 10:56:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 13:52:54

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 21:42:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-15T17:12:08', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'efb25927-42ad-4f85-b5a7-41ae4d6fbb12'	System	15 Sep 2020 22:12:37
User entered 'Yes (Y)'	System	15 Sep 2020 22:12:37

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-15T17:12:20', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'efb25927-42ad-4f85-b5a7-41ae4d6fbb12'	System	15 Sep 2020 22:12:37
User entered '96.5'	System	15 Sep 2020 22:12:37

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-15T17:12:27', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'efb25927-42ad-4f85-b5a7-41ae4d6fbb12'	System	15 Sep 2020 22:12:37
User entered 'No (N)'	System	15 Sep 2020 22:12:37

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-15T17:12:35', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'efb25927-42ad-4f85-b5a7-41ae4d6fbb12'	System	15 Sep 2020 22:12:37
User entered '15 Sep 2020 17:12'	System	15 Sep 2020 22:12:37

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 16:53'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 19:23'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 21:42:14
User entered 'Day 1, after vaccination (at home)'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T09:33:13', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'fafec64e-49d3-4366-8e64-46511a79e84e'	System	16 Sep 2020 14:33:42
User entered 'Yes (Y)'	System	16 Sep 2020 14:33:42

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T09:33:24', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'fafec64e-49d3-4366-8e64-46511a79e84e' User entered '96.5'	System	16 Sep 2020 14:33:42
	System	16 Sep 2020 14:33:42

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T09:33:28', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'fafec64e-49d3-4366-8e64-46511a79e84e'	System	16 Sep 2020 14:33:42
User entered 'No (N)'	System	16 Sep 2020 14:33:42

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T09:33:38', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'fafec64e-49d3-4366-8e64-46511a79e84e' User entered '16 Sep 2020 09:33'	System	16 Sep 2020 14:33:42
	System	16 Sep 2020 14:33:42

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 20:18'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 21:42:14
User entered 'Day 2'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:56:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T15:29:40', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '5571920d-8ba4-4ed8-a7ba-a35a9f2ebdb4'	System	16 Sep 2020 20:30:07
User entered 'Yes (Y)'	System	16 Sep 2020 20:30:07

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:56:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T15:29:46', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '5571920d-8ba4-4ed8-a7ba-a35a9f2ebdb4' User entered '97.4'	System	16 Sep 2020 20:30:07
	System	16 Sep 2020 20:30:07

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:56:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T15:29:50', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '5571920d-8ba4-4ed8-a7ba-a35a9f2ebdb4'	System	16 Sep 2020 20:30:07
User entered 'No (N)'	System	16 Sep 2020 20:30:07

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:56:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T15:29:59', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '5571920d-8ba4-4ed8-a7ba-a35a9f2ebdb4'	System	16 Sep 2020 20:30:07
User entered '16 Sep 2020 15:29'	System	16 Sep 2020 20:30:07

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:56:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:56:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 21:42:14
User entered 'Day 3'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:56:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-17T17:17:49', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '3fa8d362-1a4b-451e-9a93-1c859da22193'	System	17 Sep 2020 22:18:14
User entered 'Yes (Y)'	System	17 Sep 2020 22:18:14

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:56:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-17T17:17:55', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '3fa8d362-1a4b-451e-9a93-1c859da22193' User entered '96.3'	System	17 Sep 2020 22:18:14

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:56:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-17T17:17:59', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '3fa8d362-1a4b-451e-9a93-1c859da22193'	System	17 Sep 2020 22:18:14
User entered 'No (N)'	System	17 Sep 2020 22:18:14

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:56:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-17T17:18:11', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '3fa8d362-1a4b-451e-9a93-1c859da22193'	System	17 Sep 2020 22:18:14
User entered '17 Sep 2020 17:18'	System	17 Sep 2020 22:18:14

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:56:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:56:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 21:42:14
User entered 'Day 4'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:56:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-18T15:06:12', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'ef51ba3e-f805-4c52-a271-e1af5b73fe38'	System	18 Sep 2020 20:06:32
User entered 'Yes (Y)'	System	18 Sep 2020 20:06:32

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:56:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-18T15:06:19', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'ef51ba3e-f805-4c52-a271-e1af5b73fe38'	System	18 Sep 2020 20:06:32
User entered '97.9'	System	18 Sep 2020 20:06:32

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:56:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-18T15:06:24', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'ef51ba3e-f805-4c52-a271-e1af5b73fe38'	System	18 Sep 2020 20:06:32
User entered 'No (N)'	System	18 Sep 2020 20:06:32

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:56:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-18T15:06:30', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'ef51ba3e-f805-4c52-a271-e1af5b73fe38'	System	18 Sep 2020 20:06:32
User entered '18 Sep 2020 15:06'	System	18 Sep 2020 20:06:32

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:56:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:56:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 21:42:14
User entered 'Day 5'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:56:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-19T14:51:00', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'd0f5dd79-adde-4570-8f19-d6e8d8685dc5'	System	19 Sep 2020 19:51:23
User entered 'Yes (Y)'	System	19 Sep 2020 19:51:23

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:56:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-19T14:51:10', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'd0f5dd79-adde-4570-8f19-d6e8d8685dc5'	System	19 Sep 2020 19:51:23
User entered '97.4'	System	19 Sep 2020 19:51:23

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:56:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-19T14:51:15', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'd0f5dd79-adde-4570-8f19-d6e8d8685dc5'	System	19 Sep 2020 19:51:23
User entered 'No (N)'	System	19 Sep 2020 19:51:23

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:56:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-19T14:51:21', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'd0f5dd79-adde-4570-8f19-d6e8d8685dc5'	System	19 Sep 2020 19:51:23
User entered '19 Sep 2020 14:51'	System	19 Sep 2020 19:51:23

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:56:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:56:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 21:42:14
User entered 'Day 6'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:56:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-20T13:29:48', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'da6adeaa-d473-4faf-a303-dd325826c2da'	System	20 Sep 2020 18:30:06
User entered 'Yes (Y)'	System	20 Sep 2020 18:30:06

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:56:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-20T13:29:54', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'da6adeaa-d473-4faf-a303-dd325826c2da' User entered '97.3'	System	20 Sep 2020 18:30:06
	System	20 Sep 2020 18:30:06

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:56:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-20T13:29:58', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'da6adeaa-d473-4faf-a303-dd325826c2da'	System	20 Sep 2020 18:30:06
User entered 'No (N)'	System	20 Sep 2020 18:30:06

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:56:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-20T13:30:03', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'da6adeaa-d473-4faf-a303-dd325826c2da' User entered '20 Sep 2020 13:30'	System	20 Sep 2020 18:30:06
	System	20 Sep 2020 18:30:06

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:56:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 12:00'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:56:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:59'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 21:42:14
User entered 'Day 7'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:56:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-21T13:20:38', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'b897487a-4fb7-4a71-a861-e4ba954cc1d7'	System	21 Sep 2020 18:20:56
User entered 'Yes (Y)'	System	21 Sep 2020 18:20:56

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:56:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-21T13:20:44', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'b897487a-4fb7-4a71-a861-e4ba954cc1d7'	System	21 Sep 2020 18:20:56
User entered '96.4'	System	21 Sep 2020 18:20:56

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:56:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-21T13:20:49', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'b897487a-4fb7-4a71-a861-e4ba954cc1d7'	System	21 Sep 2020 18:20:56
User entered 'No (N)'	System	21 Sep 2020 18:20:56

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:56:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-21T13:20:53', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'b897487a-4fb7-4a71-a861-e4ba954cc1d7'	System	21 Sep 2020 18:20:56
User entered '21 Sep 2020 13:20'	System	21 Sep 2020 18:20:56

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:56:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 12:00'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:56:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 11:59'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 21:42:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-15T17:12:58', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '733db319-248f-493a-aae1-dc9fe54a8444'	System	15 Sep 2020 22:14:49
User entered 'None (1)'	System	15 Sep 2020 22:14:49

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-15T17:14:29', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '733db319-248f-493a-aae1-dc9fe54a8444'	System	15 Sep 2020 22:14:49
User entered 'No (N)'	System	15 Sep 2020 22:14:49

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-15T17:14:33', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '733db319-248f-493a-aae1-dc9fe54a8444'	System	15 Sep 2020 22:14:49
User entered 'No (N)'	System	15 Sep 2020 22:14:49

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-15T17:14:43', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '733db319-248f-493a-aae1-dc9fe54a8444'	System	15 Sep 2020 22:14:49
User entered 'None (1)'	System	15 Sep 2020 22:14:49

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-15T17:14:47', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '733db319-248f-493a-aae1-dc9fe54a8444'	System	15 Sep 2020 22:14:49
User entered '15 Sep 2020 17:14'	System	15 Sep 2020 22:14:49

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 16:53'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 19:23'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 21:42:14
User entered 'Day 1, after vaccination (at home)'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T09:33:47', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '899554f1-7ff6-4230-bb67-4ad184db9437'	System	16 Sep 2020 14:34:53
User entered 'None (1)'	System	16 Sep 2020 14:34:53

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T09:34:26', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '899554f1-7ff6-4230-bb67-4ad184db9437'	System	16 Sep 2020 14:34:53
User entered 'No (N)'	System	16 Sep 2020 14:34:53

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T09:34:33', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '899554f1-7ff6-4230-bb67-4ad184db9437'	System	16 Sep 2020 14:34:53
User entered 'No (N)'	System	16 Sep 2020 14:34:53

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T09:34:44', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '899554f1-7ff6-4230-bb67-4ad184db9437'	System	16 Sep 2020 14:34:53
User entered 'None (1)'	System	16 Sep 2020 14:34:53

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T09:34:49', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '899554f1-7ff6-4230-bb67-4ad184db9437'	System	16 Sep 2020 14:34:53
User entered '16 Sep 2020 09:34'	System	16 Sep 2020 14:34:53

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 20:18'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 21:42:14
User entered 'Day 2'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:56:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T15:30:08', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '8b543ac0-6d4d-4051-bad6-0dc4b31a9018'	System	16 Sep 2020 20:31:03
User entered 'None (1)'	System	16 Sep 2020 20:31:03

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:56:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T15:30:35', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '8b543ac0-6d4d-4051-bad6-0dc4b31a9018'	System	16 Sep 2020 20:31:03
User entered 'No (N)'	System	16 Sep 2020 20:31:03

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:56:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T15:30:39', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '8b543ac0-6d4d-4051-bad6-0dc4b31a9018'	System	16 Sep 2020 20:31:03
User entered 'No (N)'	System	16 Sep 2020 20:31:03

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:56:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T15:30:46', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '8b543ac0-6d4d-4051-bad6-0dc4b31a9018'	System	16 Sep 2020 20:31:03
User entered 'None (1)'	System	16 Sep 2020 20:31:03

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:56:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T15:31:00', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '8b543ac0-6d4d-4051-bad6-0dc4b31a9018'	System	16 Sep 2020 20:31:03
User entered '16 Sep 2020 15:31'	System	16 Sep 2020 20:31:03

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:56:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:56:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 21:42:14
User entered 'Day 3'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:56:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-17T17:18:22', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '00b05d53-b9af-4a65-9fd9-d76113c0e9b6'	System	17 Sep 2020 22:18:48
User entered 'None (1)'	System	17 Sep 2020 22:18:48

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:56:38

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-17T17:18:26', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '00b05d53-b9af-4a65-9fd9-d76113c0e9b6'	System	17 Sep 2020 22:18:48
User entered 'No (N)'	System	17 Sep 2020 22:18:48

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:56:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-17T17:18:31', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '00b05d53-b9af-4a65-9fd9-d76113c0e9b6'	System	17 Sep 2020 22:18:48
User entered 'No (N)'	System	17 Sep 2020 22:18:48

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:56:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-17T17:18:43', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '00b05d53-b9af-4a65-9fd9-d76113c0e9b6'	System	17 Sep 2020 22:18:48
User entered 'None (1)'	System	17 Sep 2020 22:18:48

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:56:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-17T17:18:47', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '00b05d53-b9af-4a65-9fd9-d76113c0e9b6'	System	17 Sep 2020 22:18:48
User entered '17 Sep 2020 17:18'	System	17 Sep 2020 22:18:48

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:56:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:56:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 21:42:14
User entered 'Day 4'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:56:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-18T15:06:36', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '417f35b8-a48b-4cdc-9530-1b5b410e3926'	System	18 Sep 2020 20:07:06
User entered 'None (1)'	System	18 Sep 2020 20:07:06

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:56:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-18T15:06:40', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '417f35b8-a48b-4cdc-9530-1b5b410e3926'	System	18 Sep 2020 20:07:06
User entered 'No (N)'	System	18 Sep 2020 20:07:06

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:56:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-18T15:06:47', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '417f35b8-a48b-4cdc-9530-1b5b410e3926'	System	18 Sep 2020 20:07:06
User entered 'No (N)'	System	18 Sep 2020 20:07:06

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:56:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-18T15:06:59', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '417f35b8-a48b-4cdc-9530-1b5b410e3926'	System	18 Sep 2020 20:07:06
User entered 'None (1)'	System	18 Sep 2020 20:07:06

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:56:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-18T15:07:02', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '417f35b8-a48b-4cdc-9530-1b5b410e3926' User entered '18 Sep 2020 15:07'	System	18 Sep 2020 20:07:06
	System	18 Sep 2020 20:07:06

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:56:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:56:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 21:42:14
User entered 'Day 5'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:56:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-19T14:51:26', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '99bac4db-2498-44e6-b165-7fbf612b779c'	System	19 Sep 2020 19:51:49
User entered 'None (1)'	System	19 Sep 2020 19:51:49

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:56:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-19T14:51:29', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '99bac4db-2498-44e6-b165-7fbf612b779c'	System	19 Sep 2020 19:51:49
User entered 'No (N)'	System	19 Sep 2020 19:51:49

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:56:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-19T14:51:32', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '99bac4db-2498-44e6-b165-7fbf612b779c'	System	19 Sep 2020 19:51:49
User entered 'No (N)'	System	19 Sep 2020 19:51:49

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:56:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-19T14:51:38', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '99bac4db-2498-44e6-b165-7fbf612b779c'	System	19 Sep 2020 19:51:49
User entered 'None (1)'	System	19 Sep 2020 19:51:49

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:56:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-19T14:51:47', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '99bac4db-2498-44e6-b165-7fbf612b779c'	System	19 Sep 2020 19:51:49
User entered '19 Sep 2020 14:51'	System	19 Sep 2020 19:51:49

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:56:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:56:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 21:42:14
User entered 'Day 6'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:56:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-20T13:30:10', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '7c67e03f-a68e-40df-bbee-45ad625de9de'	System	20 Sep 2020 18:30:31
User entered 'None (1)'	System	20 Sep 2020 18:30:31

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:56:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-20T13:30:13', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '7c67e03f-a68e-40df-bbee-45ad625de9de'	System	20 Sep 2020 18:30:31
User entered 'No (N)'	System	20 Sep 2020 18:30:31

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:56:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-20T13:30:19', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '7c67e03f-a68e-40df-bbee-45ad625de9de'	System	20 Sep 2020 18:30:31
User entered 'No (N)'	System	20 Sep 2020 18:30:31

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:56:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-20T13:30:27', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '7c67e03f-a68e-40df-bbee-45ad625de9de'	System	20 Sep 2020 18:30:31
User entered 'None (1)'	System	20 Sep 2020 18:30:31

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:56:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-20T13:30:30', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '7c67e03f-a68e-40df-bbee-45ad625de9de' User entered '20 Sep 2020 13:30'	System	20 Sep 2020 18:30:31
	System	20 Sep 2020 18:30:31

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:56:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 12:00'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:56:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:59'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 21:42:14
User entered 'Day 7'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:56:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-21T13:20:59', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '0a3eccf2-254a-4f58-9e5d-87fb366b99e3'	System	21 Sep 2020 18:21:16
User entered 'None (1)'	System	21 Sep 2020 18:21:16

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:56:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-21T13:21:02', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '0a3eccf2-254a-4f58-9e5d-87fb366b99e3'	System	21 Sep 2020 18:21:16
User entered 'No (N)'	System	21 Sep 2020 18:21:16

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:56:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-21T13:21:05', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '0a3eccf2-254a-4f58-9e5d-87fb366b99e3'	System	21 Sep 2020 18:21:16
User entered 'No (N)'	System	21 Sep 2020 18:21:16

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:56:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-21T13:21:09', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '0a3eccf2-254a-4f58-9e5d-87fb366b99e3'	System	21 Sep 2020 18:21:16
User entered 'None (1)'	System	21 Sep 2020 18:21:16

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:56:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-21T13:21:12', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '0a3eccf2-254a-4f58-9e5d-87fb366b99e3'	System	21 Sep 2020 18:21:16
User entered '21 Sep 2020 13:21'	System	21 Sep 2020 18:21:16

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:56:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 12:00'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:56:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 11:59'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 21:42:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-15T17:15:00', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '62f79bcd-2cbf-4d65-bd85-39c965349ea1' User entered 'None (0)'	System	15 Sep 2020 22:15:50
	System	15 Sep 2020 22:15:50

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-15T17:15:05', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '62f79bcd-2cbf-4d65-bd85-39c965349ea1' User entered 'None (0)'	System	15 Sep 2020 22:15:50
	System	15 Sep 2020 22:15:50

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-15T17:15:09', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '62f79bcd-2cbf-4d65-bd85-39c965349ea1' User entered 'None (0)'	System	15 Sep 2020 22:15:50
	System	15 Sep 2020 22:15:50

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-15T17:15:15', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '62f79bcd-2cbf-4d65-bd85-39c965349ea1' User entered 'None (0)'	System	15 Sep 2020 22:15:50
	System	15 Sep 2020 22:15:50

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-15T17:15:18', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '62f79bcd-2cbf-4d65-bd85-39c965349ea1' User entered 'None (0)'	System	15 Sep 2020 22:15:50
	System	15 Sep 2020 22:15:50

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-15T17:15:30', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '62f79bcd-2cbf-4d65-bd85-39c965349ea1' User entered 'None (0)'	System	15 Sep 2020 22:15:50
	System	15 Sep 2020 22:15:50

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-15T17:15:42', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '62f79bcd-2cbf-4d65-bd85-39c965349ea1' User entered 'No (N)'	System	15 Sep 2020 22:15:50
	System	15 Sep 2020 22:15:50

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-15T17:15:45', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '62f79bcd-2cbf-4d65-bd85-39c965349ea1' User entered '15 Sep 2020 17:15'	System	15 Sep 2020 22:15:50
	System	15 Sep 2020 22:15:50

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 16:53'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 19:23'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 21:42:14
User entered 'Day 1, after vaccination (at home)'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T09:34:54', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'f3d562b9-7f5d-48b8-860b-a4c6f23a876b'	System	16 Sep 2020 14:35:34
User entered 'None (0)'	System	16 Sep 2020 14:35:34

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T09:34:58', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'f3d562b9-7f5d-48b8-860b-a4c6f23a876b'	System	16 Sep 2020 14:35:34
User entered 'None (0)'	System	16 Sep 2020 14:35:34

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T09:35:02', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'f3d562b9-7f5d-48b8-860b-a4c6f23a876b'	System	16 Sep 2020 14:35:34
User entered 'None (0)'	System	16 Sep 2020 14:35:34

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T09:35:06', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'f3d562b9-7f5d-48b8-860b-a4c6f23a876b'	System	16 Sep 2020 14:35:34
User entered 'None (0)'	System	16 Sep 2020 14:35:34

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T09:35:10', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'f3d562b9-7f5d-48b8-860b-a4c6f23a876b'	System	16 Sep 2020 14:35:34
User entered 'None (0)'	System	16 Sep 2020 14:35:34

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T09:35:14', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'f3d562b9-7f5d-48b8-860b-a4c6f23a876b'	System	16 Sep 2020 14:35:34
User entered 'None (0)'	System	16 Sep 2020 14:35:34

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T09:35:26', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'f3d562b9-7f5d-48b8-860b-a4c6f23a876b'	System	16 Sep 2020 14:35:34
User entered 'No (N)'	System	16 Sep 2020 14:35:34

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T09:35:29', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'f3d562b9-7f5d-48b8-860b-a4c6f23a876b'	System	16 Sep 2020 14:35:34
User entered '16 Sep 2020 09:35'	System	16 Sep 2020 14:35:34

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 20:18'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 21:42:14
User entered 'Day 2'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T15:31:07', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '9f94942d-448f-4d23-95d5-66363334b190'	System	16 Sep 2020 20:31:41
User entered 'None (0)'	System	16 Sep 2020 20:31:41

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T15:31:11', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '9f94942d-448f-4d23-95d5-66363334b190'	System	16 Sep 2020 20:31:41
User entered 'None (0)'	System	16 Sep 2020 20:31:41

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T15:31:16', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '9f94942d-448f-4d23-95d5-66363334b190'	System	16 Sep 2020 20:31:41
User entered 'None (0)'	System	16 Sep 2020 20:31:41

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T15:31:20', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '9f94942d-448f-4d23-95d5-66363334b190'	System	16 Sep 2020 20:31:41
User entered 'None (0)'	System	16 Sep 2020 20:31:41

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T15:31:23', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '9f94942d-448f-4d23-95d5-66363334b190'	System	16 Sep 2020 20:31:41
User entered 'None (0)'	System	16 Sep 2020 20:31:41

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T15:31:27', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '9f94942d-448f-4d23-95d5-66363334b190'	System	16 Sep 2020 20:31:41
User entered 'None (0)'	System	16 Sep 2020 20:31:41

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T15:31:33', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '9f94942d-448f-4d23-95d5-66363334b190'	System	16 Sep 2020 20:31:41
User entered 'No (N)'	System	16 Sep 2020 20:31:41

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-16T15:31:37', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '9f94942d-448f-4d23-95d5-66363334b190'	System	16 Sep 2020 20:31:41
User entered '16 Sep 2020 15:31'	System	16 Sep 2020 20:31:41

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 21:42:14
User entered 'Day 3'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-17T17:18:54', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '7e970e0a-a488-46fd-98d8-7d201c24de61'	System	17 Sep 2020 22:19:24
User entered 'None (0)'	System	17 Sep 2020 22:19:24

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-17T17:18:57', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '7e970e0a-a488-46fd-98d8-7d201c24de61'	System	17 Sep 2020 22:19:24
User entered 'None (0)'	System	17 Sep 2020 22:19:24

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-17T17:19:02', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '7e970e0a-a488-46fd-98d8-7d201c24de61'	System	17 Sep 2020 22:19:24
User entered 'None (0)'	System	17 Sep 2020 22:19:24

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-17T17:19:07', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '7e970e0a-a488-46fd-98d8-7d201c24de61'	System	17 Sep 2020 22:19:24
User entered 'None (0)'	System	17 Sep 2020 22:19:24

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-17T17:19:12', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '7e970e0a-a488-46fd-98d8-7d201c24de61'	System	17 Sep 2020 22:19:24
User entered 'None (0)'	System	17 Sep 2020 22:19:24

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-17T17:19:15', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '7e970e0a-a488-46fd-98d8-7d201c24de61' User entered 'None (0)'	System	17 Sep 2020 22:19:24
	System	17 Sep 2020 22:19:24

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-17T17:19:19', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '7e970e0a-a488-46fd-98d8-7d201c24de61'	System	17 Sep 2020 22:19:24
User entered 'No (N)'	System	17 Sep 2020 22:19:24

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-17T17:19:23', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '7e970e0a-a488-46fd-98d8-7d201c24de61'	System	17 Sep 2020 22:19:24
User entered '17 Sep 2020 17:19'	System	17 Sep 2020 22:19:24

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 21:42:14
User entered 'Day 4'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-18T15:07:08', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '489e432e-9f1b-49be-ac9f-b1c425065d8b' User entered 'None (0)'	System	18 Sep 2020 20:07:37
	System	18 Sep 2020 20:07:37

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-18T15:07:10', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '489e432e-9f1b-49be-ac9f-b1c425065d8b' User entered 'None (0)'	System	18 Sep 2020 20:07:37
	System	18 Sep 2020 20:07:37

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-18T15:07:13', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '489e432e-9f1b-49be-ac9f-b1c425065d8b' User entered 'None (0)'	System	18 Sep 2020 20:07:37
	System	18 Sep 2020 20:07:37

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-18T15:07:16', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '489e432e-9f1b-49be-ac9f-b1c425065d8b' User entered 'None (0)'	System	18 Sep 2020 20:07:37
	System	18 Sep 2020 20:07:37

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-18T15:07:23', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '489e432e-9f1b-49be-ac9f-b1c425065d8b' User entered 'None (0)'	System	18 Sep 2020 20:07:37
	System	18 Sep 2020 20:07:37

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-18T15:07:26', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '489e432e-9f1b-49be-ac9f-b1c425065d8b' User entered 'None (0)'	System	18 Sep 2020 20:07:37
	System	18 Sep 2020 20:07:37

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-18T15:07:31', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '489e432e-9f1b-49be-ac9f-b1c425065d8b'	System	18 Sep 2020 20:07:37
User entered 'No (N)'	System	18 Sep 2020 20:07:37

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-18T15:07:34', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '489e432e-9f1b-49be-ac9f-b1c425065d8b' User entered '18 Sep 2020 15:07'	System	18 Sep 2020 20:07:37
	System	18 Sep 2020 20:07:37

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 21:42:14
User entered 'Day 5'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-19T14:51:54', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '0fbd3729-0f86-4fe7-8eba-3390cc5a5415'	System	19 Sep 2020 19:52:23
User entered 'None (0)'	System	19 Sep 2020 19:52:23

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-19T14:51:57', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '0fbd3729-0f86-4fe7-8eba-3390cc5a5415'	System	19 Sep 2020 19:52:23
User entered 'None (0)'	System	19 Sep 2020 19:52:23

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-19T14:52:00', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '0fbd3729-0f86-4fe7-8eba-3390cc5a5415'	System	19 Sep 2020 19:52:23
User entered 'None (0)'	System	19 Sep 2020 19:52:23

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-19T14:52:03', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '0fbd3729-0f86-4fe7-8eba-3390cc5a5415'	System	19 Sep 2020 19:52:23
User entered 'None (0)'	System	19 Sep 2020 19:52:23

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-19T14:52:07', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '0fbd3729-0f86-4fe7-8eba-3390cc5a5415'	System	19 Sep 2020 19:52:23
User entered 'None (0)'	System	19 Sep 2020 19:52:23

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-19T14:52:11', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '0fbd3729-0f86-4fe7-8eba-3390cc5a5415'	System	19 Sep 2020 19:52:23
User entered 'None (0)'	System	19 Sep 2020 19:52:23

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-19T14:52:15', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '0fbd3729-0f86-4fe7-8eba-3390cc5a5415'	System	19 Sep 2020 19:52:23
User entered 'No (N)'	System	19 Sep 2020 19:52:23

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-19T14:52:22', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '0fbd3729-0f86-4fe7-8eba-3390cc5a5415'	System	19 Sep 2020 19:52:23
User entered '19 Sep 2020 14:52'	System	19 Sep 2020 19:52:23

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 21:42:14
User entered 'Day 6'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-20T13:30:34', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'f7008c3d-4c58-4200-b6da-e1c566994b1b'	System	20 Sep 2020 18:31:25
User entered 'None (0)'	System	20 Sep 2020 18:31:25

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-20T13:30:37', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'f7008c3d-4c58-4200-b6da-e1c566994b1b'	System	20 Sep 2020 18:31:25
User entered 'None (0)'	System	20 Sep 2020 18:31:25

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-20T13:30:40', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'f7008c3d-4c58-4200-b6da-e1c566994b1b' User entered 'None (0)'	System	20 Sep 2020 18:31:25
	System	20 Sep 2020 18:31:25

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-20T13:30:43', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'f7008c3d-4c58-4200-b6da-e1c566994b1b' User entered 'None (0)'	System	20 Sep 2020 18:31:25
	System	20 Sep 2020 18:31:25

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-20T13:30:46', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'f7008c3d-4c58-4200-b6da-e1c566994b1b' User entered 'None (0)'	System	20 Sep 2020 18:31:25
	System	20 Sep 2020 18:31:25

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-20T13:30:48', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'f7008c3d-4c58-4200-b6da-e1c566994b1b' User entered 'None (0)'	System	20 Sep 2020 18:31:25
	System	20 Sep 2020 18:31:25

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-20T13:31:11', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'f7008c3d-4c58-4200-b6da-e1c566994b1b' User entered 'Yes (Y)'	System	20 Sep 2020 18:31:25
	System	20 Sep 2020 18:31:25

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-20T13:31:23', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'f7008c3d-4c58-4200-b6da-e1c566994b1b' User entered '20 Sep 2020 13:31'	System	20 Sep 2020 18:31:25
	System	20 Sep 2020 18:31:25

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 12:00'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:59'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 21:42:14
User entered 'Day 7'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-21T13:21:19', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'af135bc3-a3db-40b4-b903-9b5c04d7af9a'	System	21 Sep 2020 18:21:44
User entered 'None (0)'	System	21 Sep 2020 18:21:44

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-21T13:21:21', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'af135bc3-a3db-40b4-b903-9b5c04d7af9a'	System	21 Sep 2020 18:21:44
User entered 'None (0)'	System	21 Sep 2020 18:21:44

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-21T13:21:23', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'af135bc3-a3db-40b4-b903-9b5c04d7af9a'	System	21 Sep 2020 18:21:44
User entered 'None (0)'	System	21 Sep 2020 18:21:44

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-21T13:21:26', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'af135bc3-a3db-40b4-b903-9b5c04d7af9a'	System	21 Sep 2020 18:21:44
User entered 'None (0)'	System	21 Sep 2020 18:21:44

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-21T13:21:28', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'af135bc3-a3db-40b4-b903-9b5c04d7af9a'	System	21 Sep 2020 18:21:44
User entered 'None (0)'	System	21 Sep 2020 18:21:44

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-21T13:21:32', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'af135bc3-a3db-40b4-b903-9b5c04d7af9a'	System	21 Sep 2020 18:21:44
User entered 'None (0)'	System	21 Sep 2020 18:21:44

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-21T13:21:38', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'af135bc3-a3db-40b4-b903-9b5c04d7af9a'	System	21 Sep 2020 18:21:44
User entered 'No (N)'	System	21 Sep 2020 18:21:44

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-09-21T13:21:43', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'af135bc3-a3db-40b4-b903-9b5c04d7af9a'	System	21 Sep 2020 18:21:44
User entered '21 Sep 2020 13:21'	System	21 Sep 2020 18:21:44

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 12:00'	System	15 Sep 2020 21:42:14

US3322353

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 11:59'	System	15 Sep 2020 21:42:14

US3322353

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	22 Sep 2020 16:52:16

US3322353

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:38

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	22 Sep 2020 16:52:16

US3322353

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4) (b) (4)	22 Sep 2020 16:52:16

US3322353

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	22 Sep 2020 16:52:16

US3322353

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	22 Sep 2020 16:52:20

US3322353

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Sep 2020 16:52:20

US3322353

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	30 Sep 2020 17:36:42

US3322353

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	30 Sep 2020 17:36:42

US3322353

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4) (b) (4)	30 Sep 2020 17:36:42

US3322353

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	30 Sep 2020 17:36:42

US3322353

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	30 Sep 2020 17:36:57

US3322353

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Sep 2020 17:36:57

US3322353

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	06 Oct 2020 19:49:26

US3322353

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '6 Oct 2020'	Elisa Moralez (b) (4) (b) (4)	06 Oct 2020 19:49:26

US3322353

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4) (b) (4)	06 Oct 2020 19:49:26

US3322353

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	06 Oct 2020 19:49:26

US3322353

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	06 Oct 2020 19:49:29

US3322353

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Oct 2020 19:49:29

US3322353

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:56:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:18:08

US3322353

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:56:38

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 20:18:08

US3322353

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:56:38

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	13 Oct 2020 20:18:08

US3322353

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:56:38

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	13 Oct 2020 20:18:08

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:38

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:38

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User entered '13:09'	(b) (4), (b) (6)	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 13:09'	System	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:38

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.4' F	(b) (4), (b) (6)	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:38

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:38

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '68'	(b) (4), (b) (6)	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:38

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '15'	(b) (4), (b) (6)	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '128'	(b) (4), (b) (6)	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '78'	(b) (4), (b) (6)	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 10:56:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:38

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:38

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User entered '14:40'	(b) (4), (b) (6)	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 14:40'	System	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:38

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.8' F	(b) (4), (b) (6)	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:38

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:38

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '54'	(b) (4), (b) (6)	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:38

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '146'	(b) (4), (b) (6)	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '83'	(b) (4), (b) (6)	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 10:56:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Oct 2020 20:19:20

US3322353

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:56:38

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:19:31

US3322353

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:56:38

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 20:19:31

US3322353

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:56:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	13 Oct 2020 19:07:49

US3322353

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:56:38

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	13 Oct 2020 19:07:49

US3322353

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:56:38

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	13 Oct 2020 19:07:49

US3322353

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:56:38

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	13 Oct 2020 19:07:49

US3322353

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:56:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Frances Saubon (b) (4) (b) (4)	13 Oct 2020 19:07:49

US3322353

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:56:38

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '14:03'	Frances Saubon (b) (4) (b) (4)	13 Oct 2020 19:07:49

US3322353

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:56:38

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 14:03'	System	13 Oct 2020 19:07:49

US3322353

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:56:38

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Frances Saubon (b) (4) (b) (4)	13 Oct 2020 19:07:49

US3322353

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:56:38

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
User entered 'ONCE'	System	13 Oct 2020 19:07:49

US3322353

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 10:56:38

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	13 Oct 2020 19:07:49

US3322353

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:56:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:19:52

US3322353

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:56:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 20:19:52

US3322353

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:56:38

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '13:55'	(b) (4), (b) (6)	13 Oct 2020 20:19:52

US3322353

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:56:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 13:55'	System	13 Oct 2020 20:19:52

US3322353

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 10:56:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 20:20:07

US3322353

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:56:38

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	13 Oct 2020 20:20:07

US3322353

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:56:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:20:07

US3322353

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:56:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '13:50'	(b) (4), (b) (6)	13 Oct 2020 20:20:07

US3322353

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 10:56:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 13:50'	System	13 Oct 2020 20:20:07

US3322353

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:56:38

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	13 Oct 2020 20:20:07

US3322353

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:56:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 20:20:07

US3322353

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:56:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:20:07

US3322353

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 10:56:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 20:20:07

US3322353

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:20:14

US3322353

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Oct 2020 20:20:14

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 19:07:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T14:40:31', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '9b2fb5be-af2f-4c49-a4e5-ce60391e5911'	System	13 Oct 2020 19:41:01
User entered 'Yes (Y)'	System	13 Oct 2020 19:41:01

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T14:40:40', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '9b2fb5be-af2f-4c49-a4e5-ce60391e5911'	System	13 Oct 2020 19:41:01
User entered '97.8'	System	13 Oct 2020 19:41:01

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T14:40:48', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '9b2fb5be-af2f-4c49-a4e5-ce60391e5911'	System	13 Oct 2020 19:41:01
User entered 'No (N)'	System	13 Oct 2020 19:41:01

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T14:40:55', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '9b2fb5be-af2f-4c49-a4e5-ce60391e5911'	System	13 Oct 2020 19:41:01
User entered '13 Oct 2020 14:40'	System	13 Oct 2020 19:41:01

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 14:23'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 16:53'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 19:07:49
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T18:46:47', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '49d9fc22-c937-4b1f-8814-3e253f1e3187'	System	13 Oct 2020 23:47:17
User entered 'Yes (Y)'	System	13 Oct 2020 23:47:17

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T18:47:06', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '49d9fc22-c937-4b1f-8814-3e253f1e3187'	System	13 Oct 2020 23:47:17
User entered '97.2'	System	13 Oct 2020 23:47:17

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T18:47:10', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '49d9fc22-c937-4b1f-8814-3e253f1e3187'	System	13 Oct 2020 23:47:17
User entered 'No (N)'	System	13 Oct 2020 23:47:17

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T18:47:13', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '49d9fc22-c937-4b1f-8814-3e253f1e3187'	System	13 Oct 2020 23:47:17
User entered '13 Oct 2020 18:47'	System	13 Oct 2020 23:47:17

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 17:48'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 19:07:49
User entered 'Day 2'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:56:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-14T13:01:53', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '98eb37cf-27c2-4da3-ae65-c7c702220d0c'	System	14 Oct 2020 18:02:20
User entered 'Yes (Y)'	System	14 Oct 2020 18:02:20

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:56:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-14T13:02:08', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '98eb37cf-27c2-4da3-ae65-c7c702220d0c' User entered '98.3'	System	14 Oct 2020 18:02:20
	System	14 Oct 2020 18:02:20

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:56:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-14T13:02:13', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '98eb37cf-27c2-4da3-ae65-c7c702220d0c'	System	14 Oct 2020 18:02:20
User entered 'No (N)'	System	14 Oct 2020 18:02:20

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:56:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-14T13:02:17', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '98eb37cf-27c2-4da3-ae65-c7c702220d0c' User entered '14 Oct 2020 13:02'	System	14 Oct 2020 18:02:20
	System	14 Oct 2020 18:02:20

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:56:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 10:56:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 19:07:49
User entered 'Day 3'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:56:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-15T14:15:46', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'f7ee2aa3-957d-4047-8bbd-61f3a84b44f2'	System	15 Oct 2020 19:16:05
User entered 'Yes (Y)'	System	15 Oct 2020 19:16:05

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:56:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-15T14:15:53', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'f7ee2aa3-957d-4047-8bbd-61f3a84b44f2'	System	15 Oct 2020 19:16:05
User entered '97.9'	System	15 Oct 2020 19:16:05

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:56:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-15T14:15:58', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'f7ee2aa3-957d-4047-8bbd-61f3a84b44f2'	System	15 Oct 2020 19:16:05
User entered 'No (N)'	System	15 Oct 2020 19:16:05

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:56:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-15T14:16:02', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'f7ee2aa3-957d-4047-8bbd-61f3a84b44f2'	System	15 Oct 2020 19:16:05
User entered '15 Oct 2020 14:16'	System	15 Oct 2020 19:16:05

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:56:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 10:56:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 19:07:49
User entered 'Day 4'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:56:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-16T16:17:43', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'd4e5a61f-1139-4c22-847f-83c2644e3f43'	System	16 Oct 2020 21:18:07
User entered 'Yes (Y)'	System	16 Oct 2020 21:18:07

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:56:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-16T16:17:50', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'd4e5a61f-1139-4c22-847f-83c2644e3f43'	System	16 Oct 2020 21:18:07
User entered '97.1'	System	16 Oct 2020 21:18:07

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:56:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-16T16:17:58', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'd4e5a61f-1139-4c22-847f-83c2644e3f43'	System	16 Oct 2020 21:18:07
User entered 'No (N)'	System	16 Oct 2020 21:18:07

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:56:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-16T16:18:02', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'd4e5a61f-1139-4c22-847f-83c2644e3f43'	System	16 Oct 2020 21:18:07
User entered '16 Oct 2020 16:18'	System	16 Oct 2020 21:18:07

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:56:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 10:56:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 19:07:49
User entered 'Day 5'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:56:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-17T17:49:22', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'b5e1f105-dce1-42d6-a2fd-b1971b7f9f84'	System	17 Oct 2020 22:49:43
User entered 'Yes (Y)'	System	17 Oct 2020 22:49:43

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:56:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-17T17:49:30', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'b5e1f105-dce1-42d6-a2fd-b1971b7f9f84'	System	17 Oct 2020 22:49:43
User entered '97.6'	System	17 Oct 2020 22:49:43

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:56:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-17T17:49:36', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'b5e1f105-dce1-42d6-a2fd-b1971b7f9f84'	System	17 Oct 2020 22:49:43
User entered 'No (N)'	System	17 Oct 2020 22:49:43

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:56:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-17T17:49:40', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'b5e1f105-dce1-42d6-a2fd-b1971b7f9f84'	System	17 Oct 2020 22:49:43
User entered '17 Oct 2020 17:49'	System	17 Oct 2020 22:49:43

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:56:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 10:56:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 19:07:49
User entered 'Day 6'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:56:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-18T16:36:02', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'e1d56946-148b-4ebd-b428-dfa5fc03e960'	System	18 Oct 2020 21:36:18
User entered 'Yes (Y)'	System	18 Oct 2020 21:36:18

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:56:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-18T16:36:08', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'e1d56946-148b-4ebd-b428-dfa5fc03e960'	System	18 Oct 2020 21:36:18
User entered '97.6'	System	18 Oct 2020 21:36:18

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:56:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-18T16:36:12', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'e1d56946-148b-4ebd-b428-dfa5fc03e960'	System	18 Oct 2020 21:36:18
User entered 'No (N)'	System	18 Oct 2020 21:36:18

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:56:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-18T16:36:16', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'e1d56946-148b-4ebd-b428-dfa5fc03e960'	System	18 Oct 2020 21:36:18
User entered '18 Oct 2020 16:36'	System	18 Oct 2020 21:36:18

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:56:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 10:56:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 19:07:49
User entered 'Day 7'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:56:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-19T13:39:09', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '80b91e50-7595-431c-a723-88ff5bd9613c' User entered 'Yes (Y)'	System	19 Oct 2020 18:39:24
	System	19 Oct 2020 18:39:24

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:56:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-19T13:39:15', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '80b91e50-7595-431c-a723-88ff5bd9613c' User entered '98.4'	System	19 Oct 2020 18:39:24

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:56:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-19T13:39:17', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '80b91e50-7595-431c-a723-88ff5bd9613c'	System	19 Oct 2020 18:39:24
User entered 'No (N)'	System	19 Oct 2020 18:39:24

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:56:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-19T13:39:20', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '80b91e50-7595-431c-a723-88ff5bd9613c' User entered '19 Oct 2020 13:39'	System	19 Oct 2020 18:39:24
	System	19 Oct 2020 18:39:24

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:56:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 10:56:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 19:07:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T14:41:04', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '88ae58bd-bdd1-48f7-ba76-a5166904a0d0'	System	13 Oct 2020 19:41:28
User entered 'None (1)'	System	13 Oct 2020 19:41:28

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T14:41:10', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '88ae58bd-bdd1-48f7-ba76-a5166904a0d0'	System	13 Oct 2020 19:41:28
User entered 'No (N)'	System	13 Oct 2020 19:41:28

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T14:41:15', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '88ae58bd-bdd1-48f7-ba76-a5166904a0d0'	System	13 Oct 2020 19:41:28
User entered 'No (N)'	System	13 Oct 2020 19:41:28

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T14:41:22', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '88ae58bd-bdd1-48f7-ba76-a5166904a0d0'	System	13 Oct 2020 19:41:28
User entered 'None (1)'	System	13 Oct 2020 19:41:28

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T14:41:25', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '88ae58bd-bdd1-48f7-ba76-a5166904a0d0' User entered '13 Oct 2020 14:41'	System	13 Oct 2020 19:41:28
	System	13 Oct 2020 19:41:28

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 14:23'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 16:53'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 19:07:49
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T18:45:35', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'aa590651-0ceb-4b0c-b16a-60a5c726eccd'	System	13 Oct 2020 23:46:00
User entered 'Does not interfere with activity (2)'	System	13 Oct 2020 23:46:00

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T18:45:39', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'aa590651-0ceb-4b0c-b16a-60a5c726eccd'	System	13 Oct 2020 23:46:00
User entered 'No (N)'	System	13 Oct 2020 23:46:00

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T18:45:50', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'aa590651-0ceb-4b0c-b16a-60a5c726eccd'	System	13 Oct 2020 23:46:00
User entered 'No (N)'	System	13 Oct 2020 23:46:00

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T18:45:54', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'aa590651-0ceb-4b0c-b16a-60a5c726eccd'	System	13 Oct 2020 23:46:00
User entered 'None (1)'	System	13 Oct 2020 23:46:00

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T18:45:58', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'aa590651-0ceb-4b0c-b16a-60a5c726eccd'	System	13 Oct 2020 23:46:00
User entered '13 Oct 2020 18:45'	System	13 Oct 2020 23:46:00

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 17:48'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 19:07:49
User entered 'Day 2'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:56:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-14T13:02:27', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'bad58e5a-0b61-4f2a-9408-e0ee4dd8cb78'	System	14 Oct 2020 18:03:11
User entered 'Does not interfere with activity (2)'	System	14 Oct 2020 18:03:11

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:56:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-14T13:02:31', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'bad58e5a-0b61-4f2a-9408-e0ee4dd8cb78'	System	14 Oct 2020 18:03:11
User entered 'No (N)'	System	14 Oct 2020 18:03:11

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:56:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-14T13:02:33', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'bad58e5a-0b61-4f2a-9408-e0ee4dd8cb78'	System	14 Oct 2020 18:03:11
User entered 'No (N)'	System	14 Oct 2020 18:03:11

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:56:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-14T13:02:38', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'bad58e5a-0b61-4f2a-9408-e0ee4dd8cb78'	System	14 Oct 2020 18:03:11
User entered 'None (1)'	System	14 Oct 2020 18:03:11

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:56:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-14T13:02:41', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'bad58e5a-0b61-4f2a-9408-e0ee4dd8cb78' User entered '14 Oct 2020 13:02'	System	14 Oct 2020 18:03:11
	System	14 Oct 2020 18:03:11

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:56:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 10:56:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 19:07:49
User entered 'Day 3'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:56:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-15T14:16:11', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'e2b5cf7b-b620-45b1-8ee3-9508734b845c'	System	15 Oct 2020 19:16:35
User entered 'None (1)'	System	15 Oct 2020 19:16:35

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:56:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-15T14:16:14', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'e2b5cf7b-b620-45b1-8ee3-9508734b845c'	System	15 Oct 2020 19:16:35
User entered 'No (N)'	System	15 Oct 2020 19:16:35

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:56:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-15T14:16:17', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'e2b5cf7b-b620-45b1-8ee3-9508734b845c' User entered 'No (N)'	System	15 Oct 2020 19:16:35
	System	15 Oct 2020 19:16:35

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:56:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-15T14:16:25', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'e2b5cf7b-b620-45b1-8ee3-9508734b845c' User entered 'None (1)'	System	15 Oct 2020 19:16:35
	System	15 Oct 2020 19:16:35

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:56:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-15T14:16:28', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'e2b5cf7b-b620-45b1-8ee3-9508734b845c' User entered '15 Oct 2020 14:16'	System	15 Oct 2020 19:16:35
	System	15 Oct 2020 19:16:35

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:56:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 10:56:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 19:07:49
User entered 'Day 4'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:56:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-16T16:18:06', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'dfcf4f31-a9c5-452f-bf4f-75c7104fb102'	System	16 Oct 2020 21:18:23
User entered 'None (1)'	System	16 Oct 2020 21:18:23

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:56:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-16T16:18:09', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'dfcf4f31-a9c5-452f-bf4f-75c7104fb102'	System	16 Oct 2020 21:18:23
User entered 'No (N)'	System	16 Oct 2020 21:18:23

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:56:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-16T16:18:11', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'dfcf4f31-a9c5-452f-bf4f-75c7104fb102'	System	16 Oct 2020 21:18:23
User entered 'No (N)'	System	16 Oct 2020 21:18:23

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:56:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-16T16:18:18', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'dfcf4f31-a9c5-452f-bf4f-75c7104fb102'	System	16 Oct 2020 21:18:23
User entered 'None (1)'	System	16 Oct 2020 21:18:23

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:56:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-16T16:18:20', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'dfcf4f31-a9c5-452f-bf4f-75c7104fb102'	System	16 Oct 2020 21:18:23
User entered '16 Oct 2020 16:18'	System	16 Oct 2020 21:18:23

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:56:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 10:56:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 19:07:49
User entered 'Day 5'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:56:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-17T17:49:44', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'e9797e3c-8ac1-43db-8095-fb11cbbc8813'	System	17 Oct 2020 22:49:56
User entered 'None (1)'	System	17 Oct 2020 22:49:56

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:56:38

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-17T17:49:47', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'e9797e3c-8ac1-43db-8095-fb11cbbc8813'	System	17 Oct 2020 22:49:56
User entered 'No (N)'	System	17 Oct 2020 22:49:56

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:56:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-17T17:49:49', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'e9797e3c-8ac1-43db-8095-fb11cbbc8813'	System	17 Oct 2020 22:49:56
User entered 'No (N)'	System	17 Oct 2020 22:49:56

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:56:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-17T17:49:51', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'e9797e3c-8ac1-43db-8095-fb11cbbc8813'	System	17 Oct 2020 22:49:56
User entered 'None (1)'	System	17 Oct 2020 22:49:56

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:56:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-17T17:49:54', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'e9797e3c-8ac1-43db-8095-fb11cbbc8813' User entered '17 Oct 2020 17:49'	System	17 Oct 2020 22:49:56
	System	17 Oct 2020 22:49:56

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:56:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 10:56:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 19:07:49
User entered 'Day 6'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:56:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-18T16:36:19', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'eeaad3d7-7587-4cf9-a12f-119b28d16d4e'	System	18 Oct 2020 21:36:36
User entered 'None (1)'	System	18 Oct 2020 21:36:36

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:56:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-18T16:36:22', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'eeaad3d7-7587-4cf9-a12f-119b28d16d4e'	System	18 Oct 2020 21:36:36
User entered 'No (N)'	System	18 Oct 2020 21:36:36

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:56:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-18T16:36:24', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'eeaad3d7-7587-4cf9-a12f-119b28d16d4e'	System	18 Oct 2020 21:36:36
User entered 'No (N)'	System	18 Oct 2020 21:36:36

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:56:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-18T16:36:26', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'eeaad3d7-7587-4cf9-a12f-119b28d16d4e'	System	18 Oct 2020 21:36:36
User entered 'None (1)'	System	18 Oct 2020 21:36:36

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:56:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-18T16:36:28', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'eeaad3d7-7587-4cf9-a12f-119b28d16d4e' User entered '18 Oct 2020 16:36'	System	18 Oct 2020 21:36:36
	System	18 Oct 2020 21:36:36

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:56:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 10:56:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 19:07:49
User entered 'Day 7'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:56:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-19T13:39:25', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'de964231-0ed6-406d-b3d8-8d64bd4f36c9'	System	19 Oct 2020 18:39:38
User entered 'None (1)'	System	19 Oct 2020 18:39:38

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:56:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-19T13:39:28', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'de964231-0ed6-406d-b3d8-8d64bd4f36c9'	System	19 Oct 2020 18:39:38
User entered 'No (N)'	System	19 Oct 2020 18:39:38

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:56:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-19T13:39:30', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'de964231-0ed6-406d-b3d8-8d64bd4f36c9'	System	19 Oct 2020 18:39:38
User entered 'No (N)'	System	19 Oct 2020 18:39:38

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:56:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-19T13:39:34', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'de964231-0ed6-406d-b3d8-8d64bd4f36c9'	System	19 Oct 2020 18:39:38
User entered 'None (1)'	System	19 Oct 2020 18:39:38

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:56:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-19T13:39:36', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'de964231-0ed6-406d-b3d8-8d64bd4f36c9'	System	19 Oct 2020 18:39:38
User entered '19 Oct 2020 13:39'	System	19 Oct 2020 18:39:38

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:56:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 10:56:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 19:07:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T14:41:30', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '01b9bddf-4ba7-42de-b076-b9aeae7b028c' User entered 'None (0)'	System	13 Oct 2020 19:41:54
	System	13 Oct 2020 19:41:54

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T14:41:34', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '01b9bddf-4ba7-42de-b076-b9aeae7b028c' User entered 'None (0)'	System	13 Oct 2020 19:41:54
	System	13 Oct 2020 19:41:54

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T14:41:37', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '01b9bddf-4ba7-42de-b076-b9aeae7b028c' User entered 'None (0)'	System	13 Oct 2020 19:41:54
	System	13 Oct 2020 19:41:54

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T14:41:39', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '01b9bddf-4ba7-42de-b076-b9aeae7b028c' User entered 'None (0)'	System	13 Oct 2020 19:41:54
	System	13 Oct 2020 19:41:54

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T14:41:41', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '01b9bddf-4ba7-42de-b076-b9aeae7b028c'	System	13 Oct 2020 19:41:54
User entered 'None (0)'	System	13 Oct 2020 19:41:54

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T14:41:44', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '01b9bddf-4ba7-42de-b076-b9aeae7b028c' User entered 'None (0)'	System	13 Oct 2020 19:41:54
	System	13 Oct 2020 19:41:54

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T14:41:49', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '01b9bddf-4ba7-42de-b076-b9aeae7b028c' User entered 'No (N)'	System	13 Oct 2020 19:41:54

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T14:41:51', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '01b9bddf-4ba7-42de-b076-b9aeae7b028c' User entered '13 Oct 2020 14:41'	System	13 Oct 2020 19:41:54
	System	13 Oct 2020 19:41:54

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 14:23'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 10:56:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 16:53'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 19:07:49
User entered 'Day 1, after vaccination (at home)'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T18:46:05', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'd5424783-55da-4e62-be82-4a8bde25a5ea' User entered 'None (0)'	System	13 Oct 2020 23:46:28
	System	13 Oct 2020 23:46:28

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T18:46:07', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'd5424783-55da-4e62-be82-4a8bde25a5ea' User entered 'None (0)'	System	13 Oct 2020 23:46:28
	System	13 Oct 2020 23:46:28

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T18:46:10', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'd5424783-55da-4e62-be82-4a8bde25a5ea' User entered 'None (0)'	System	13 Oct 2020 23:46:28
	System	13 Oct 2020 23:46:28

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T18:46:13', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'd5424783-55da-4e62-be82-4a8bde25a5ea' User entered 'None (0)'	System	13 Oct 2020 23:46:28
	System	13 Oct 2020 23:46:28

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T18:46:16', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'd5424783-55da-4e62-be82-4a8bde25a5ea' User entered 'None (0)'	System	13 Oct 2020 23:46:28
	System	13 Oct 2020 23:46:28

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T18:46:18', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'd5424783-55da-4e62-be82-4a8bde25a5ea' User entered 'None (0)'	System	13 Oct 2020 23:46:28
	System	13 Oct 2020 23:46:28

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T18:46:23', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'd5424783-55da-4e62-be82-4a8bde25a5ea' User entered 'No (N)'	System	13 Oct 2020 23:46:28
	System	13 Oct 2020 23:46:28

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-13T18:46:26', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'd5424783-55da-4e62-be82-4a8bde25a5ea' User entered '13 Oct 2020 18:46'	System	13 Oct 2020 23:46:28
	System	13 Oct 2020 23:46:28

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Oct 2020 17:48'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 10:56:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 11:59'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 19:07:49
User entered 'Day 2'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-14T13:02:46', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'afbb763e-ac3f-4e3f-87e2-f70b0adb12b6'	System	14 Oct 2020 18:03:13
User entered 'None (0)'	System	14 Oct 2020 18:03:13

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-14T13:02:49', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'afbb763e-ac3f-4e3f-87e2-f70b0adb12b6'	System	14 Oct 2020 18:03:13
User entered 'None (0)'	System	14 Oct 2020 18:03:13

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-14T13:02:51', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'afbb763e-ac3f-4e3f-87e2-f70b0adb12b6'	System	14 Oct 2020 18:03:13
User entered 'None (0)'	System	14 Oct 2020 18:03:13

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-14T13:02:54', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'afbb763e-ac3f-4e3f-87e2-f70b0adb12b6' User entered 'None (0)'	System	14 Oct 2020 18:03:13

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-14T13:02:58', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'afbb763e-ac3f-4e3f-87e2-f70b0adb12b6'	System	14 Oct 2020 18:03:13
User entered 'None (0)'	System	14 Oct 2020 18:03:13

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-14T13:03:01', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'afbb763e-ac3f-4e3f-87e2-f70b0adb12b6'	System	14 Oct 2020 18:03:13
User entered 'None (0)'	System	14 Oct 2020 18:03:13

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-14T13:03:04', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'afbb763e-ac3f-4e3f-87e2-f70b0adb12b6'	System	14 Oct 2020 18:03:13
User entered 'No (N)'	System	14 Oct 2020 18:03:13

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-14T13:03:11', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'afbb763e-ac3f-4e3f-87e2-f70b0adb12b6' User entered '14 Oct 2020 13:03'	System	14 Oct 2020 18:03:13

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Oct 2020 12:00'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 10:56:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 11:59'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 19:07:49
User entered 'Day 3'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-15T14:16:33', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '116f4d80-32ea-48f8-9a3f-553752c3f33b'	System	15 Oct 2020 19:16:58
User entered 'None (0)'	System	15 Oct 2020 19:16:58

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-15T14:16:36', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '116f4d80-32ea-48f8-9a3f-553752c3f33b' User entered 'None (0)'	System	15 Oct 2020 19:16:58

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-15T14:16:38', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '116f4d80-32ea-48f8-9a3f-553752c3f33b'	System	15 Oct 2020 19:16:58
User entered 'None (0)'	System	15 Oct 2020 19:16:58

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-15T14:16:41', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '116f4d80-32ea-48f8-9a3f-553752c3f33b' User entered 'None (0)'	System	15 Oct 2020 19:16:58
	System	15 Oct 2020 19:16:58

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-15T14:16:44', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '116f4d80-32ea-48f8-9a3f-553752c3f33b'	System	15 Oct 2020 19:16:58
User entered 'None (0)'	System	15 Oct 2020 19:16:58

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-15T14:16:46', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '116f4d80-32ea-48f8-9a3f-553752c3f33b' User entered 'None (0)'	System	15 Oct 2020 19:16:58
	System	15 Oct 2020 19:16:58

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-15T14:16:50', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '116f4d80-32ea-48f8-9a3f-553752c3f33b' User entered 'No (N)'	System	15 Oct 2020 19:16:58
	System	15 Oct 2020 19:16:58

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-15T14:16:55', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '116f4d80-32ea-48f8-9a3f-553752c3f33b'	System	15 Oct 2020 19:16:58
User entered '15 Oct 2020 14:16'	System	15 Oct 2020 19:16:58

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 10:56:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 19:07:49
User entered 'Day 4'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-16T16:18:25', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'fa975a77-e53c-450a-99ae-4b5a6286a2f6'	System	16 Oct 2020 21:18:44
User entered 'None (0)'	System	16 Oct 2020 21:18:44

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-16T16:18:27', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'fa975a77-e53c-450a-99ae-4b5a6286a2f6'	System	16 Oct 2020 21:18:44
User entered 'None (0)'	System	16 Oct 2020 21:18:44

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-16T16:18:29', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'fa975a77-e53c-450a-99ae-4b5a6286a2f6'	System	16 Oct 2020 21:18:44
User entered 'None (0)'	System	16 Oct 2020 21:18:44

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-16T16:18:31', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'fa975a77-e53c-450a-99ae-4b5a6286a2f6'	System	16 Oct 2020 21:18:44
User entered 'None (0)'	System	16 Oct 2020 21:18:44

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-16T16:18:33', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'fa975a77-e53c-450a-99ae-4b5a6286a2f6'	System	16 Oct 2020 21:18:44
User entered 'None (0)'	System	16 Oct 2020 21:18:44

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-16T16:18:35', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'fa975a77-e53c-450a-99ae-4b5a6286a2f6'	System	16 Oct 2020 21:18:44
User entered 'None (0)'	System	16 Oct 2020 21:18:44

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-16T16:18:40', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'fa975a77-e53c-450a-99ae-4b5a6286a2f6'	System	16 Oct 2020 21:18:44
User entered 'No (N)'	System	16 Oct 2020 21:18:44

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-16T16:18:42', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'fa975a77-e53c-450a-99ae-4b5a6286a2f6'	System	16 Oct 2020 21:18:44
User entered '16 Oct 2020 16:18'	System	16 Oct 2020 21:18:44

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Oct 2020 12:00'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 10:56:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 11:59'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 19:07:49
User entered 'Day 5'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-17T17:49:57', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'e2c08dfe-f7a0-49eb-82fd-bdf910904e4d'	System	17 Oct 2020 22:50:16
User entered 'None (0)'	System	17 Oct 2020 22:50:16

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-17T17:49:59', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'e2c08dfe-f7a0-49eb-82fd-bdf910904e4d'	System	17 Oct 2020 22:50:16
User entered 'None (0)'	System	17 Oct 2020 22:50:16

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-17T17:50:01', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'e2c08dfe-f7a0-49eb-82fd-bdf910904e4d'	System	17 Oct 2020 22:50:16
User entered 'None (0)'	System	17 Oct 2020 22:50:16

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-17T17:50:03', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'e2c08dfe-f7a0-49eb-82fd-bdf910904e4d'	System	17 Oct 2020 22:50:16
User entered 'None (0)'	System	17 Oct 2020 22:50:16

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-17T17:50:04', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'e2c08dfe-f7a0-49eb-82fd-bdf910904e4d'	System	17 Oct 2020 22:50:16
User entered 'None (0)'	System	17 Oct 2020 22:50:16

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-17T17:50:06', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'e2c08dfe-f7a0-49eb-82fd-bdf910904e4d'	System	17 Oct 2020 22:50:16
User entered 'None (0)'	System	17 Oct 2020 22:50:16

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-17T17:50:10', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'e2c08dfe-f7a0-49eb-82fd-bdf910904e4d'	System	17 Oct 2020 22:50:16
User entered 'No (N)'	System	17 Oct 2020 22:50:16

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-17T17:50:12', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: 'e2c08dfe-f7a0-49eb-82fd-bdf910904e4d' User entered '17 Oct 2020 17:50'	System	17 Oct 2020 22:50:16
	System	17 Oct 2020 22:50:16

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Oct 2020 12:00'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 10:56:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 11:59'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 19:07:49
User entered 'Day 6'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-18T16:36:32', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '15c37c0e-8344-456a-9997-61214a792434'	System	18 Oct 2020 21:36:49
User entered 'None (0)'	System	18 Oct 2020 21:36:49

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-18T16:36:34', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '15c37c0e-8344-456a-9997-61214a792434'	System	18 Oct 2020 21:36:49
User entered 'None (0)'	System	18 Oct 2020 21:36:49

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-18T16:36:35', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '15c37c0e-8344-456a-9997-61214a792434'	System	18 Oct 2020 21:36:49
User entered 'None (0)'	System	18 Oct 2020 21:36:49

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-18T16:36:37', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '15c37c0e-8344-456a-9997-61214a792434'	System	18 Oct 2020 21:36:49
User entered 'None (0)'	System	18 Oct 2020 21:36:49

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-18T16:36:39', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '15c37c0e-8344-456a-9997-61214a792434'	System	18 Oct 2020 21:36:49
User entered 'None (0)'	System	18 Oct 2020 21:36:49

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-18T16:36:41', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '15c37c0e-8344-456a-9997-61214a792434'	System	18 Oct 2020 21:36:49
User entered 'None (0)'	System	18 Oct 2020 21:36:49

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-18T16:36:44', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '15c37c0e-8344-456a-9997-61214a792434'	System	18 Oct 2020 21:36:49
User entered 'No (N)'	System	18 Oct 2020 21:36:49

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-18T16:36:46', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '15c37c0e-8344-456a-9997-61214a792434' User entered '18 Oct 2020 16:36'	System	18 Oct 2020 21:36:49
	System	18 Oct 2020 21:36:49

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Oct 2020 12:00'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 10:56:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 11:59'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	13 Oct 2020 19:07:49
User entered 'Day 7'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:38

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-19T13:39:41', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '79ecdb69-17da-46b9-868a-7593946425c0'	System	19 Oct 2020 18:40:00
User entered 'None (0)'	System	19 Oct 2020 18:40:00

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:38

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-19T13:39:43', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '79ecdb69-17da-46b9-868a-7593946425c0'	System	19 Oct 2020 18:40:00
User entered 'None (0)'	System	19 Oct 2020 18:40:00

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-19T13:39:45', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '79ecdb69-17da-46b9-868a-7593946425c0'	System	19 Oct 2020 18:40:00
User entered 'None (0)'	System	19 Oct 2020 18:40:00

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-19T13:39:46', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '79ecdb69-17da-46b9-868a-7593946425c0'	System	19 Oct 2020 18:40:00
User entered 'None (0)'	System	19 Oct 2020 18:40:00

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-19T13:39:48', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '79ecdb69-17da-46b9-868a-7593946425c0'	System	19 Oct 2020 18:40:00
User entered 'None (0)'	System	19 Oct 2020 18:40:00

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:38

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-19T13:39:51', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '79ecdb69-17da-46b9-868a-7593946425c0'	System	19 Oct 2020 18:40:00
User entered 'None (0)'	System	19 Oct 2020 18:40:00

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-19T13:39:53', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '79ecdb69-17da-46b9-868a-7593946425c0'	System	19 Oct 2020 18:40:00
User entered 'No (N)'	System	19 Oct 2020 18:40:00

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:38

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-10-19T13:39:56', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '79ecdb69-17da-46b9-868a-7593946425c0'	System	19 Oct 2020 18:40:00
User entered '19 Oct 2020 13:39'	System	19 Oct 2020 18:40:00

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 12:00'	System	13 Oct 2020 19:07:49

US3322353

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 10:56:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Oct 2020 11:59'	System	13 Oct 2020 19:07:49

US3322353

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	20 Oct 2020 17:20:10

US3322353

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '20 Oct 2020'	Elisa Moralez (b) (4) (b) (4)	20 Oct 2020 17:20:10

US3322353

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4) (b) (4)	20 Oct 2020 17:20:10

US3322353

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	20 Oct 2020 17:20:10

US3322353

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	20 Oct 2020 17:20:02

US3322353

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Oct 2020 17:20:02

US3322353

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	28 Oct 2020 16:50:23

US3322353

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '27 Oct 2020'	Elisa Moralez (b) (4) (b) (4)	28 Oct 2020 16:50:23

US3322353

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4) (b) (4)	28 Oct 2020 16:50:23

US3322353

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	28 Oct 2020 16:50:23

US3322353

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	28 Oct 2020 16:50:26

US3322353

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Oct 2020 16:50:26

US3322353

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	05 Nov 2020 18:34:04

US3322353

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '4 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	05 Nov 2020 18:34:04

US3322353

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4) (b) (4)	05 Nov 2020 18:34:04

US3322353

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 10:56:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	05 Nov 2020 18:34:04

US3322353

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	05 Nov 2020 18:33:55

US3322353

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Nov 2020 18:33:55

US3322353

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:56:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 20:05:36

US3322353

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:56:38

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '10 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 20:05:36

US3322353

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:56:38

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	10 Nov 2020 20:05:36

US3322353

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 10:56:38

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	10 Nov 2020 20:05:36

US3322353

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 20:06:06

US3322353

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 20:06:06

US3322353

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:38

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User entered '12:05'	(b) (4), (b) (6)	10 Nov 2020 20:06:06

US3322353

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '10 Nov 2020 12:05'	System	10 Nov 2020 20:06:06

US3322353

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:38

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.5' F	(b) (4), (b) (6)	10 Nov 2020 20:06:06

US3322353

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:38

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	10 Nov 2020 20:06:06

US3322353

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:38

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 20:06:06

US3322353

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '78'	(b) (4), (b) (6)	10 Nov 2020 20:06:06

US3322353

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:38

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	10 Nov 2020 20:06:06

US3322353

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '15'	(b) (4), (b) (6)	10 Nov 2020 20:06:06

US3322353

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	10 Nov 2020 20:06:06

US3322353

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '112'	(b) (4), (b) (6)	10 Nov 2020 20:06:06

US3322353

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Nov 2020 20:06:06

US3322353

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '72'	(b) (4), (b) (6)	10 Nov 2020 20:06:06

US3322353

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 10:56:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Nov 2020 20:06:06

US3322353

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:56:38

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 20:06:16

US3322353

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 10:56:38

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 20:06:16

US3322353

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:56:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 20:06:27

US3322353

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:56:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Nov 2020'	(b) (4), (b) (6)	10 Nov 2020 20:06:27

US3322353

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:56:38

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '13:07'	(b) (4), (b) (6)	10 Nov 2020 20:06:27

US3322353

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 10:56:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '10 Nov 2020 13:07'	System	10 Nov 2020 20:06:27

US3322353

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Nov 2020 20:06:32

US3322353

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 10:56:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Nov 2020 20:06:32

US3322353

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 21:42:14
User entered 'Day 64'	System	15 Sep 2020 21:42:14

US3322353

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-11-16T12:47:04', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '2b0e99eb-5140-49e8-a3e8-65a8f71e519a'	System	16 Nov 2020 18:47:22
User entered 'No (N)'	System	16 Nov 2020 18:47:22

US3322353

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-11-16T12:47:13', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '2b0e99eb-5140-49e8-a3e8-65a8f71e519a'	System	16 Nov 2020 18:47:22
User entered 'No (N)'	System	16 Nov 2020 18:47:22

US3322353

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-11-16T12:47:18', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '2b0e99eb-5140-49e8-a3e8-65a8f71e519a' User entered '16 Nov 2020 12:47:18'	System	16 Nov 2020 18:47:22
	System	16 Nov 2020 18:47:22

US3322353

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 21:42:14
User entered '15 Nov 2020 00:01'	System	15 Sep 2020 21:42:14

US3322353

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	15 Sep 2020 21:42:14
User entered '19 Nov 2020 23:59'	System	15 Sep 2020 21:42:14

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '12 Nov 2020 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '16 Nov 2020 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-11-23T12:44:09', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '5a2fc9f2-ed3a-40eb-ba72-3b69ddb9e590'	System	23 Nov 2020 18:44:57
User entered 'No (N)'	System	23 Nov 2020 18:44:57

US3322353

Folder: New Safety Follow Up Diary (1)

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[Have you been exposed to someone with 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 (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-11-23T12:44:24', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '5a2fc9f2-ed3a-40eb-ba72-3b69ddb9e590'	System	23 Nov 2020 18:44:57
User entered 'Yes (Y)'	System	23 Nov 2020 18:44:57

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-11-23T12:44:32', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '5a2fc9f2-ed3a-40eb-ba72-3b69ddb9e590'	System	23 Nov 2020 18:44:57
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	23 Nov 2020 18:44:57

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (72F63582-7A3C-4BAE-B1B5-7122E351A06B)', Time: '2020-11-23T12:44:46', User OID: 'PatientReportedOutcome (US3322353)', ODM File OID: '5a2fc9f2-ed3a-40eb-ba72-3b69ddb9e590' User entered '23 Nov 2020 12:44:46'	System	23 Nov 2020 18:44:57
	System	23 Nov 2020 18:44:57

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '19 Nov 2020 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '23 Nov 2020 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '26 Nov 2020 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '30 Nov 2020 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '03 Dec 2020 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '07 Dec 2020 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '10 Dec 2020 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '14 Dec 2020 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '17 Dec 2020 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '21 Dec 2020 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '24 Dec 2020 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '28 Dec 2020 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '31 Dec 2020 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '04 Jan 2021 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '07 Jan 2021 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '11 Jan 2021 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '14 Jan 2021 00:01'	System	20 Nov 2020 08:47:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '18 Jan 2021 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 08:47:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '21 Jan 2021 00:01'	System	20 Nov 2020 08:47:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '25 Jan 2021 23:59'	System	20 Nov 2020 08:47:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 08:47:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '28 Jan 2021 00:01'	System	20 Nov 2020 08:47:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '01 Feb 2021 23:59'	System	20 Nov 2020 08:47:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 08:47:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '04 Feb 2021 00:01'	System	20 Nov 2020 08:47:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '08 Feb 2021 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 08:47:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '11 Feb 2021 00:01'	System	20 Nov 2020 08:47:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '15 Feb 2021 23:59'	System	20 Nov 2020 08:47:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 08:47:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '18 Feb 2021 00:01'	System	20 Nov 2020 08:47:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '22 Feb 2021 23:59'	System	20 Nov 2020 08:47:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '25 Feb 2021 00:01'	System	20 Nov 2020 08:47:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '01 Mar 2021 23:59'	System	20 Nov 2020 08:47:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '04 Mar 2021 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '08 Mar 2021 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 08:47:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '11 Mar 2021 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '15 Mar 2021 23:59'	System	20 Nov 2020 08:47:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '18 Mar 2021 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '22 Mar 2021 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '25 Mar 2021 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '29 Mar 2021 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '01 Apr 2021 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '05 Apr 2021 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 08:47:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '08 Apr 2021 00:01'	System	20 Nov 2020 08:47:12

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '12 Apr 2021 23:59'	System	20 Nov 2020 08:47:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 08:47:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '15 Apr 2021 00:01'	System	20 Nov 2020 08:47:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '19 Apr 2021 23:59'	System	20 Nov 2020 08:47:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 08:47:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '22 Apr 2021 00:01'	System	20 Nov 2020 08:47:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '26 Apr 2021 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '29 Apr 2021 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '03 May 2021 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '06 May 2021 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '10 May 2021 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '13 May 2021 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '17 May 2021 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '20 May 2021 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '24 May 2021 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '27 May 2021 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '31 May 2021 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '03 Jun 2021 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '07 Jun 2021 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '10 Jun 2021 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '14 Jun 2021 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '17 Jun 2021 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '21 Jun 2021 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '24 Jun 2021 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '28 Jun 2021 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '01 Jul 2021 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '05 Jul 2021 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '08 Jul 2021 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '12 Jul 2021 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '15 Jul 2021 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '19 Jul 2021 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '22 Jul 2021 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '26 Jul 2021 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '29 Jul 2021 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '02 Aug 2021 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '05 Aug 2021 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '09 Aug 2021 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '12 Aug 2021 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '16 Aug 2021 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '19 Aug 2021 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '23 Aug 2021 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '26 Aug 2021 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '30 Aug 2021 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '02 Sep 2021 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '06 Sep 2021 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '09 Sep 2021 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '13 Sep 2021 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '16 Sep 2021 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '20 Sep 2021 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '23 Sep 2021 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '27 Sep 2021 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '30 Sep 2021 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '04 Oct 2021 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '07 Oct 2021 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '11 Oct 2021 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '14 Oct 2021 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '18 Oct 2021 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '21 Oct 2021 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '25 Oct 2021 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '28 Oct 2021 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '01 Nov 2021 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '04 Nov 2021 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '08 Nov 2021 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '11 Nov 2021 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '15 Nov 2021 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '18 Nov 2021 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '22 Nov 2021 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '25 Nov 2021 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '29 Nov 2021 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '02 Dec 2021 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '06 Dec 2021 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '09 Dec 2021 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '13 Dec 2021 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '16 Dec 2021 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '20 Dec 2021 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '23 Dec 2021 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '27 Dec 2021 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '30 Dec 2021 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '03 Jan 2022 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '06 Jan 2022 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '10 Jan 2022 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '13 Jan 2022 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '17 Jan 2022 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '20 Jan 2022 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '24 Jan 2022 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '27 Jan 2022 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '31 Jan 2022 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '03 Feb 2022 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '07 Feb 2022 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '10 Feb 2022 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '14 Feb 2022 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '17 Feb 2022 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '21 Feb 2022 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '24 Feb 2022 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '28 Feb 2022 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '03 Mar 2022 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '07 Mar 2022 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '10 Mar 2022 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '14 Mar 2022 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '17 Mar 2022 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '21 Mar 2022 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '24 Mar 2022 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '28 Mar 2022 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '31 Mar 2022 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '04 Apr 2022 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '07 Apr 2022 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '11 Apr 2022 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '14 Apr 2022 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '18 Apr 2022 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '21 Apr 2022 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '25 Apr 2022 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '28 Apr 2022 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '02 May 2022 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '05 May 2022 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '09 May 2022 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '12 May 2022 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '16 May 2022 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '19 May 2022 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '23 May 2022 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 08:47:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '26 May 2022 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '30 May 2022 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '02 Jun 2022 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '06 Jun 2022 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 08:47:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '09 Jun 2022 00:01'	System	20 Nov 2020 08:47:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '13 Jun 2022 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 08:47:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '16 Jun 2022 00:01'	System	20 Nov 2020 08:47:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '20 Jun 2022 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 08:47:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '23 Jun 2022 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '27 Jun 2022 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 08:47:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '30 Jun 2022 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '04 Jul 2022 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 08:47:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '07 Jul 2022 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '11 Jul 2022 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '14 Jul 2022 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '18 Jul 2022 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '21 Jul 2022 00:01'	System	20 Nov 2020 08:47:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '25 Jul 2022 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 08:47:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '28 Jul 2022 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '01 Aug 2022 23:59'	System	20 Nov 2020 08:47:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 08:47:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '04 Aug 2022 00:01'	System	20 Nov 2020 08:47:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '08 Aug 2022 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 08:47:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '11 Aug 2022 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '15 Aug 2022 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 08:47:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '18 Aug 2022 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '22 Aug 2022 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '25 Aug 2022 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '29 Aug 2022 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 08:47:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '01 Sep 2022 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '05 Sep 2022 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 08:47:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '08 Sep 2022 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '12 Sep 2022 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '15 Sep 2022 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '19 Sep 2022 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 08:47:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '22 Sep 2022 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '26 Sep 2022 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 08:47:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '29 Sep 2022 00:01'	System	20 Nov 2020 08:47:12

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '03 Oct 2022 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '06 Oct 2022 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '10 Oct 2022 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '13 Oct 2022 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '17 Oct 2022 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '20 Oct 2022 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '24 Oct 2022 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '27 Oct 2022 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '31 Oct 2022 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '03 Nov 2022 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '07 Nov 2022 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '10 Nov 2022 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '14 Nov 2022 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '17 Nov 2022 00:01'	System	20 Nov 2020 08:47:12

US3322353

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 10:56:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 08:47:12
Amendment Manager: User entered '21 Nov 2022 23:59'	System	20 Nov 2020 08:47:12

US3322353

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 10:56:38

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:24:32
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	28 Oct 2020 15:46:18

US3322353

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:38

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:35:32
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:44:26
User entered 'USA-US060-2020-mRNA-1273-P301000007'	System	29 Oct 2020 13:44:21
User entered 'New'	(b) (4), (b) (6)	29 Oct 2020 13:44:21

US3322353

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:38

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms male malignant and unspecified, HLT: Prostatic neoplasms malignant, PT: Prostate cancer, LLT: Adenocarcinoma of prostate - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 23:41:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 23:41:35
Data point term sent to Coder	System	13 Nov 2020 18:46:47
DataPoint Un-verified.	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:46:45
Coding entries removed.	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:46:45
User entered 'PROSTATE adenocarcinoma' reason for change: New Information	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:46:45
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	02 Nov 2020 22:35:32
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms male malignant and unspecified, HLT: Prostatic neoplasms malignant, PT: Prostate cancer, LLT: Prostate cancer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 18:27:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 18:27:45
Data point term sent to Coder	System	28 Oct 2020 15:49:29
User entered 'Prostate Cancer'	Frances Saubon (b) (4) (b) (4)	28 Oct 2020 15:49:02

US3322353

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:35:32
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	28 Oct 2020 15:49:02

US3322353

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:35:32
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	28 Oct 2020 15:49:02

US3322353

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:35:32
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	28 Oct 2020 15:49:02

US3322353

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:46:45
User entered '16 Oct 2020' reason for change: New Information	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:46:45
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	02 Nov 2020 22:35:32
User entered '23 Oct 2020'	Frances Saubon (b) (4) (b) (4)	28 Oct 2020 15:49:02

US3322353

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:38

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:35:32
User entered empty.	Frances Saubon (b) (4)	28 Oct 2020 15:49:02
	(b) (4)	

US3322353

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 15:49:02

US3322353

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:35:32
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	28 Oct 2020 15:49:02

US3322353

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 21:41:04
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)	10 Nov 2020 15:55:42
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 'Noted, thank you' (Site from Safety).	Frances Saubon (b) (4) (b) (4)	09 Nov 2020 14:30:42
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)	06 Nov 2020 18:02:01
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:35:32
User entered empty.	Frances Saubon (b) (4) (b) (4)	28 Oct 2020 15:49:02

US3322353

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:38

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:35:32
User entered empty.	Frances Saubon (b) (4)	28 Oct 2020 15:49:02
	(b) (4)	

US3322353

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Oct 2020 15:49:02

US3322353

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:38

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:35:32
User entered 'Grade 3/Severe (Grade 3/Severe)'	Frances Saubon (b) (4) (b) (4)	28 Oct 2020 15:49:02

US3322353

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:35:32
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	28 Oct 2020 15:49:43
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	28 Oct 2020 15:49:02
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	28 Oct 2020 15:49:02

US3322353

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:38

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:35:32
User entered '0'	Frances Saubon (b) (4) (b) (4)	28 Oct 2020 15:49:02

US3322353

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:38

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:35:32
User entered '0'	Frances Saubon (b) (4)	28 Oct 2020 15:49:02

US3322353

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:35:32
User entered '0'	Frances Saubon (b) (4) (b) (4)	28 Oct 2020 15:49:02

US3322353

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:35:32
User entered empty.	Frances Saubon (b) (4)	28 Oct 2020 15:49:02
	(b) (4)	

US3322353

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:38

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:35:32
User entered empty.	Frances Saubon (b) (4)	28 Oct 2020 15:49:02

US3322353

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:35:32
User entered empty.	Frances Saubon (b) (4)	28 Oct 2020 15:49:02

US3322353

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:35:32
User entered empty.	Frances Saubon (b) (4)	28 Oct 2020 15:49:02
	(b) (4)	

US3322353

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:35:32
User entered '0'	Frances Saubon (b) (4)	28 Oct 2020 15:49:02
	(b) (4)	

US3322353

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:35:32
User entered '0'	Frances Saubon (b) (4)	28 Oct 2020 15:49:02

US3322353

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:38

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:35:32
User entered '1' reason for change: Data Entry Error	Frances Saubon (b) (4)	28 Oct 2020 15:49:43
User entered '0'	Frances Saubon (b) (4)	28 Oct 2020 15:49:02

US3322353

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:35:32
User entered 'Not Related (NOT RELATED)'	Frances Saubon (b) (4) (b) (4)	28 Oct 2020 15:49:02

US3322353

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:35:32
User entered 'Not Related (NOT RELATED)'	Frances Saubon (b) (4) (b) (4)	28 Oct 2020 15:49:02

US3322353

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:38

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:35:32
User entered 'Not Applicable (NOT APPLICABLE)'	Frances Saubon (b) (4)	28 Oct 2020 15:49:02

US3322353

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:38

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:35:32
User entered '0'	Frances Saubon (b) (4)	28 Oct 2020 15:49:02
	(b) (4)	

US3322353

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:35:32
User entered '0'	Frances Saubon (b) (4)	28 Oct 2020 15:49:02

US3322353

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:35:32
User entered '1'	Frances Saubon (b) (4)	28 Oct 2020 15:49:02

US3322353

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:38

[Outcome](#)

Audit	User	Time (GMT)
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). DataPoint Verified.	(b) (4), (b) (6) (b) (6)	06 Nov 2020 18:02:17
	(b) (4), (b) (6) (b) (6)	02 Nov 2020 22:35:32
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Frances Saubon (b) (4) (b) (4)	28 Oct 2020 15:49:02

US3322353

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:38

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:35:32
User entered empty.	Frances Saubon (b) (4)	28 Oct 2020 15:49:02
	(b) (4)	

US3322353

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:38

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 14:20:28
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Per source: MR review reveals: hx of long-term elevated PSA, negative prostate bx 2015, PSA 5.9 7/21/2020, MRI prostate w/wo contrast 9/25/20: bladder distended with a couple of diverticula posteriorly measuring up to 1.2 cm, pronounced colonic diverticulosis, B inguinal herniorrhaphy, probability ECE approximately 24%, PI-RADS 4, BPH with obstruction/lower urinary tract symptoms, Rx cipro 500 mg bid 9/29/20 - 10/2/20 and flagyl 500 mg tid 9/29/20 - 10/2/20, prostate bx 10/16/20 adenocarcinoma Gleason 4 + 5 = 9, Revatio for pulmonary hypertension was discontinued on 11/18/2020 per his urologist. He was offered XRT/chemotherapy vs prostatectomy and decided to proceed with prostatectomy, which is scheduled 12/8/20. Discussed with Dr Fragoso and the subject remains eligible to continue in the study since he had already received his 2nd IP 10/13/20.' (Site from Safety).	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:51:35
DataPoint Un-verified.	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:47:41
User entered 'Subject called our site on 27 OCT 2020 to let us know that on Friday 23 OCT 2020 he found out that he has prostate cancer. Biopsy of prostate was on 16 OCT 2020 thus start date was changed.' reason for change: New Information	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:47:41

US3322353

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:38

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 14:41:41
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Per source, MR review reveals: hx of long-term elevated PSA, negative prostate bx 2015, PSA 5.9 7/21/2020, MRI prostate w/wo contrast 9/25/20: bladder distended with a couple of diverticula posteriorly measuring up to 1.2 cm, pronounced colonic diverticulosis, B inguinal herniorrhaphy, probability ECE approximately 24%, PI-RADS 4, BPH with obstruction/lower urinary tract symptoms Rx cipro 500 mg bid 9/29/20 - 10/2/20 and flagyl 500 mg tid 9/29/20 - 10/2/20, prostate bx 10/16/20 adenocarcinoma Gleason 4 + 5 = 9, Revatio for pulmonary hypertension discontinued 11/18/2020. Left upper extremity with no erythema, warmth, tenderness or edema, no left axillary lymphadenopathy. Discussed with PI and the subject remains eligible to continue in the study.' (Site from Safety).	Frances Saubon (b) (4) (b) (4)	10 Nov 2020 22:02:26
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 18:02:49
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 18:02:30
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:35:32
User entered 'Subject called our site on 27 OCT 2020 to let us know that on Friday 23 OCT 2020 he found out that he has prostate cancer.'	Frances Saubon (b) (4) (b) (4)	28 Oct 2020 15:49:02

US3322353

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:38

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Oct 2020 15:49:02

US3322353

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 10:56:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Oct 2020 15:49:02

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:38

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 21:18:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 21:18:42
Data point term sent to Coder	System	10 Nov 2020 21:17:28
User entered 'Gastroesophageal Reflux Disease'	Elisa Moralez (b) (4)	10 Nov 2020 21:17:01

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:01

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:01

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:01

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:38

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '03 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:01

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:38

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:01

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:17:01

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:38

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:01

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:38

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:01

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:38

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:01

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:17:01

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:38

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:01

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:01

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:38

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:01

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:38

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:01

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:01

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:01

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:38

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:01

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:01

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:01

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:01

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:01

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:38

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:01

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:01

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:01

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:38

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:01

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:38

[None](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:01

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:01

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:01

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:38

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:01

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:38

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:01

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:38

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:01

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:38

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Nov 2020 21:17:01

US3322353

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 10:56:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Nov 2020 21:17:01

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:56:38

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Lower urinary tract symptoms, LLT: Lower urinary tract symptoms - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 21:35:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 21:35:49
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Lower urinary tract symptoms, LLT: Lower urinary tract symptoms - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 21:19:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 21:19:48
Data point term sent to Coder	System	10 Nov 2020 21:18:29
User entered 'lower urinary tract symptoms'	Elisa Moralez (b) (4)	10 Nov 2020 21:17:46

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:56:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:56:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:56:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:56:38

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:56:38

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:56:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:17:46

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:56:38

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:56:38

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '02 Oct 2020'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:56:38

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:56:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:17:46

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:56:38

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:56:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:56:38

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:56:38

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:56:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:56:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:56:38

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:56:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:56:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:56:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:56:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:56:38

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:56:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:56:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:56:38

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:56:38

[None](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:56:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered 'I'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:56:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:56:38

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:56:38

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:56:38

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:17:46

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:56:38

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Nov 2020 21:17:46

US3322353

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 10:56:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	10 Nov 2020 21:17:46

US3322353

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:56:38

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Diverticular disorders, HLT: Diverticula, PT: Diverticulum intestinal, LLT: Colonic diverticulosis - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 18:46:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 18:46:49
Data point term sent to Coder	System	13 Nov 2020 18:45:42
User entered 'colonic diverticulosis'	Frances Saubon (b) (4)	13 Nov 2020 18:44:49
	(b) (4)	

US3322353

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:56:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:44:49

US3322353

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:56:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:44:49

US3322353

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:56:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:44:49

US3322353

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:56:38

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '25 Sep 2020'	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:44:49

US3322353

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:56:38

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:44:49

US3322353

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:56:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 18:44:49

US3322353

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:56:38

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:44:49

US3322353

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:56:38

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:44:49

US3322353

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:56:38

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:44:49

US3322353

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:56:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 18:44:49

US3322353

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:56:38

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:44:49

US3322353

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:56:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:44:49

US3322353

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:56:38

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:44:49

US3322353

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:56:38

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:44:49

US3322353

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:56:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:44:49

US3322353

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:56:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:44:49

US3322353

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:56:38

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:44:49

US3322353

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:56:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:44:49

US3322353

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:56:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:44:49

US3322353

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:56:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:44:49

US3322353

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:56:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:44:49

US3322353

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:56:38

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:44:49

US3322353

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:56:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:44:49

US3322353

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:56:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:44:49

US3322353

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:56:38

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:44:49

US3322353

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:56:38

None

Audit	User	Time (GMT)
User entered 'I'	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:44:49

US3322353

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:56:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:44:49

US3322353

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:56:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:44:49

US3322353

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:56:38

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:44:49

US3322353

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:56:38

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:44:49

US3322353

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:56:38

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:44:49

US3322353

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:56:38

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Nov 2020 18:44:49

US3322353

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 10:56:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Nov 2020 18:44:49

US3322353

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:56:38

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Renal and urinary disorders, HLGT: Bladder and bladder neck disorders (excl calculi), HLT: Bladder disorders NEC, PT: Bladder diverticulum, LLT: Bladder diverticulum - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 20:52:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 20:52:33
Data point term sent to Coder	System	13 Nov 2020 18:46:47
User entered 'bladder diverticula'	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:45:53

US3322353

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:56:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:45:53

US3322353

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:56:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:45:53

US3322353

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:56:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:45:53

US3322353

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:56:38

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '25 Sep 2020'	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:45:53

US3322353

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:56:38

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:45:53

US3322353

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:56:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 18:45:53

US3322353

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:56:38

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:45:53

US3322353

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:56:38

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:45:53

US3322353

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:56:38

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:45:53

US3322353

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:56:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 18:45:53

US3322353

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:56:38

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:45:53

US3322353

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:56:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:45:53

US3322353

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:56:38

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:45:53

US3322353

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:56:38

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:45:53

US3322353

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:56:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:45:53

US3322353

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:56:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:45:53

US3322353

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:56:38

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:45:53

US3322353

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:56:38

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:45:53

US3322353

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:56:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:45:53

US3322353

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:56:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:45:53

US3322353

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:56:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:45:53

US3322353

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:56:38

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:45:53

US3322353

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:56:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:45:53

US3322353

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:56:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:45:53

US3322353

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:56:38

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:45:53

US3322353

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:56:38

[None](#)

Audit	User	Time (GMT)
User entered 'I'	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:45:53

US3322353

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:56:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:45:53

US3322353

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:56:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:45:53

US3322353

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:56:38

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:45:53

US3322353

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:56:38

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:45:53

US3322353

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:56:38

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:45:53

US3322353

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:56:38

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	13 Nov 2020 18:45:53

US3322353

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 26 Nov 2020 10:56:38

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Nov 2020 18:45:53

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 10:56:38

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:16
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:48:22

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE CIPIONATE, PRODUCTSYNONYM: TESTOSTERONE CYPIONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Sep 2020 02:50:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	27 Sep 2020 02:50:49
Data point term sent to Coder	System	27 Sep 2020 02:49:42
User entered 'Testosterone cypionate'	Frances Saubon (b) (4)	27 Sep 2020 02:49:35
	(b) (4)	

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'No (N)'	Frances Saubon (b) (4)	27 Sep 2020 02:49:35
	(b) (4)	

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'erectile dysfunction'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:49:35

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:38

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the dose recorded as this is not the usual dose for this medication. Please consider recording dose in "mg" as there are multiple dose option available for this Con Med and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 19:47:17
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
Query 'Per DM CLR: Please review the dose recorded as this is not the usual dose for this medication. Please consider recording dose in "mg" as there are multiple dose option available for this Con Med and update as appropriate. ' answered with 'updated per updated source' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	30 Oct 2020 21:52:45
User entered '750' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	30 Oct 2020 21:52:34
User opened query 'Per DM CLR: Please review the dose recorded as this is not the usual dose for this medication. Please consider recording dose in "mg" as there are multiple dose option available for this Con Med and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 11:05:50
User entered '0.5'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:49:35

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'mg (mg)' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	30 Oct 2020 21:52:34
User entered 'mL (mL)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:49:35

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:38

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:49:35

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'other (OTHER)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:49:35

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'every 10 days'	Frances Saubon (b) (4)	27 Sep 2020 02:49:35
	(b) (4)	

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'Intramuscular (INTRAMUSCULAR)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:49:35

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:49:35

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'UN UNK 1987'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:49:35

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered '0'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:49:35

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:49:35

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4)	27 Sep 2020 02:49:35
	(b) (4)	

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'No (N)'	Frances Saubon (b) (4)	27 Sep 2020 02:49:35
	(b) (4)	

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Sep 2020 02:49:35

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Sep 2020 02:49:35

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 10:56:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Sep 2020 02:49:35

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: TESTOSTERONE-5-ALPHA REDUCTASE INHIBITORS, PRODUCT: FINASTERIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Sep 2020 02:51:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Sep 2020 02:51:49
Data point term sent to Coder	System	27 Sep 2020 02:50:42
User entered 'Finasteride'	Frances Saubon (b) (4)	27 Sep 2020 02:50:20

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'No (N)'	Frances Saubon (b) (4)	27 Sep 2020 02:50:20
	(b) (4)	

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'benign prostatic hyperplasia'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:50:20

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered '5'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:50:20

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'mg (mg)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:50:20

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:38

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:50:20

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'once daily (QD)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:50:20

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:50:20

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'Oral (ORAL)'	Frances Saubon (b) (4)	27 Sep 2020 02:50:20
	(b) (4)	

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4)	27 Sep 2020 02:50:20
	(b) (4)	

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'UN UNK 2014'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:50:20

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered '0'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:50:20

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:50:20

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4)	27 Sep 2020 02:50:20
	(b) (4)	

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:50:20

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Sep 2020 02:50:20

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Sep 2020 02:50:20

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 10:56:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Sep 2020 02:50:20

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: ALFUZOSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Sep 2020 02:52:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Sep 2020 02:52:50
Data point term sent to Coder	System	27 Sep 2020 02:51:42
User entered 'Alfuzosin'	Frances Saubon (b) (4)	27 Sep 2020 02:51:01

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'No (N)'	Frances Saubon (b) (4)	27 Sep 2020 02:51:01
	(b) (4)	

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'benign prostatic hyperplasia'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:51:01

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered '10'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:51:01

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'mg (mg)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:51:01

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:38

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4)	27 Sep 2020 02:51:01
	(b) (4)	

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'once daily (QD)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:51:01

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:51:01

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'Oral (ORAL)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:51:01

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:51:01

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'UN UNK 2014'	Frances Saubon (b) (4)	27 Sep 2020 02:51:01
	(b) (4)	

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered '0'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:51:01

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:51:01

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:51:01

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:51:01

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Sep 2020 02:51:01

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Sep 2020 02:51:01

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 10:56:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Sep 2020 02:51:01

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: POTASSIUM-SPARING AGENTS, ATC: OTHER POTASSIUM-SPARING AGENTS, PRODUCT: TRIAMTERENE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Nov 2020 03:51:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Nov 2020 03:51:49
Data point term sent to Coder Coding entries removed.	System Elisa Moralez (b) (4) (b) (4)	30 Oct 2020 21:51:05 30 Oct 2020 21:50:53
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: POTASSIUM-SPARING AGENTS, ATC: OTHER POTASSIUM-SPARING AGENTS, PRODUCT: TRIAMTERENE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 04:33:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 04:33:36
Data point term sent to Coder User entered 'triamterene'	System Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:52:43 27 Sep 2020 02:51:58

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'Yes (Y)'	Frances Saubon (b) (4)	27 Sep 2020 02:51:58

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:38

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 19:47:40
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
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 MH eCRF. ' answered with 'updated, thank you' (Site from DM).	Elisa Moralez (b) (4)	30 Oct 2020 21:52:11
User entered 'pedal edema' reason for change: New Information	(b) (4)	30 Oct 2020 21:50:53
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 MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 11:06:03
User entered 'edema of the feet'	Frances Saubon (b) (4)	27 Sep 2020 02:51:58

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered '25'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:51:58

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'mg (mg)'	Frances Saubon (b) (4)	27 Sep 2020 02:51:58
	(b) (4)	

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4)	27 Sep 2020 02:51:58
	(b) (4)	

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'once daily (QD)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:51:58

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:51:58

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'Oral (ORAL)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:51:58

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4)	27 Sep 2020 02:51:58
	(b) (4)	

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'UN May 2020'	Frances Saubon (b) (4)	27 Sep 2020 02:51:58
	(b) (4)	

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered '0'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:51:58

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:51:58

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:51:58

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:51:58

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Sep 2020 02:51:58

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Sep 2020 02:51:58

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 10:56:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Sep 2020 02:51:58

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
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)	27 Sep 2020 04:45:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 04:45:35
Data point term sent to Coder	System	27 Sep 2020 02:52:44
User entered 'multi vitamin'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:52:32

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'No (N)'	Frances Saubon (b) (4)	27 Sep 2020 02:52:32
	(b) (4)	

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'Supplements'	Frances Saubon (b) (4)	27 Sep 2020 02:52:32
	(b) (4)	

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered '1'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:52:32

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'tablet (TABLET)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:52:32

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:38

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4)	27 Sep 2020 02:52:32
	(b) (4)	

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'once daily (QD)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:52:32

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:52:32

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'Oral (ORAL)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:52:32

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:52:32

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'UN UNK 1975'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:52:32

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered '0'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:52:32

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:52:32

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4)	27 Sep 2020 02:52:32
	(b) (4)	

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:52:32

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Sep 2020 02:52:32

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Sep 2020 02:52:32

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 10:56:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Sep 2020 02:52:32

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: FOLIC ACID AND DERIVATIVES, PRODUCT: FOLIC ACID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 04:28:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 04:28:43
Data point term sent to Coder	System	27 Sep 2020 02:53:44
User entered 'folic acid'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:53:10

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'No (N)'	Frances Saubon (b) (4)	27 Sep 2020 02:53:10
	(b) (4)	

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'Supplements'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:53:10

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered '400'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:53:10

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:38

[Dose unit](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 19:47:54
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'updated per updated source' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	30 Oct 2020 21:50:05
User entered 'ug (ug)' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	30 Oct 2020 21:49:55
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 11:05:39
User entered 'mg (mg)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:53:10

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:38

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4)	27 Sep 2020 02:53:10
	(b) (4)	

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'once daily (QD)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:53:10

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:53:10

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'Oral (ORAL)'	Frances Saubon (b) (4)	27 Sep 2020 02:53:10
	(b) (4)	

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:53:10

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'UN UNK 1985'	Frances Saubon (b) (4)	27 Sep 2020 02:53:10
	(b) (4)	

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered '0'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:53:10

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:53:10

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:53:10

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:53:10

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Sep 2020 02:53:10

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Sep 2020 02:53:10

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 10:56:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Sep 2020 02:53:10

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:38

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)	24 Nov 2020 09:09:10
Data point term sent to Coder	(b) (4)	
Coding entries removed.	System	10 Nov 2020 21:22:34
	Elisa Moralez (b) (4)	10 Nov 2020 21:22:05
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
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)	29 Sep 2020 10:26:53
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 10:26:53
	(b) (4)	
Data point term sent to Coder	System	27 Sep 2020 02:54:45
User entered 'Metamucil'	Frances Saubon (b) (4)	27 Sep 2020 02:53:52
	(b) (4)	

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'No (N)'	Frances Saubon (b) (4)	27 Sep 2020 02:53:52
	(b) (4)	

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Elisa Moralez (b) (4)	10 Nov 2020 21:22:05
	(b) (4)	
User entered 'IRRITABLE BOWEL SYNDROME'	Elisa Moralez (b) (4)	10 Nov 2020 21:22:05
reason for change: New Information	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'irritable bowel syndrome constipation prevention'	Frances Saubon (b) (4)	27 Sep 2020 02:53:52
	(b) (4)	

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered '11000'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:53:52

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'mg (mg)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:53:52

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:38

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:53:52

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'once daily (QD)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:53:52

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:53:52

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'Oral (ORAL)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:53:52

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4)	27 Sep 2020 02:53:52
	(b) (4)	

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'UN UNK 2015'	Frances Saubon (b) (4)	27 Sep 2020 02:53:52
	(b) (4)	

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered '0'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:53:52

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:53:52

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4)	27 Sep 2020 02:53:52
	(b) (4)	

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:53:52

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Sep 2020 02:53:52

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Sep 2020 02:53:52

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 10:56:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Sep 2020 02:53:52

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:38

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: ANTIPROPULSIVES, ATC: ANTIPROPULSIVES, PRODUCT: LOPERAMIDE HYDROCHLORIDE, PRODUCTSYNONYM: IMODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 02:55:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 02:55:52
Data point term sent to Coder	System	27 Sep 2020 02:54:45
User entered 'Imodium'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:54:31

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'No (N)'	Frances Saubon (b) (4)	27 Sep 2020 02:54:31
	(b) (4)	

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'irritable bowel syndrome'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:54:31

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered '1/2'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:54:31

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'tablet (TABLET)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:54:31

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:38

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4)	27 Sep 2020 02:54:31
	(b) (4)	

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'once daily (QD)'	Frances Saubon (b) (4)	27 Sep 2020 02:54:31
	(b) (4)	

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:54:31

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'Oral (ORAL)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:54:31

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:54:31

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'UN UNK 2016'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:54:31

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered '0'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:54:31

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Elisa Moralez (b) (4)	10 Nov 2020 21:22:29
	(b) (4)	
User entered 'Yes (Y)' reason for change: New Information	Elisa Moralez (b) (4)	10 Nov 2020 21:22:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
	(b) (4), (b) (6)	
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	13 Oct 2020 20:24:00
User entered 'Yes (Y)'	Frances Saubon (b) (4)	27 Sep 2020 02:54:31
	(b) (4)	

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	Elisa Moralez (b) (4)	10 Nov 2020 21:22:29
	(b) (4)	
User entered empty; reason for change New Information	Elisa Moralez (b) (4)	10 Nov 2020 21:22:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
	(b) (4), (b) (6)	
User entered '20 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 20:24:00
	(b) (4)	
User entered empty.	Frances Saubon (b) (4)	27 Sep 2020 02:54:31
	(b) (4)	

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	27 Sep 2020 02:54:31

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Sep 2020 02:54:31

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Sep 2020 02:54:31

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 10:56:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Sep 2020 02:54:31

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:56:38

Name of Medication

Audit	User	Time (GMT)
User closed query 'Please update the concomitant procedures page. Per source, it states that the subject had a prostate biopsy on 16 Oct 2020. Please confirm and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:46:33
Query 'Please update the concomitant procedures page. Per source, it states that the subject had a prostate biopsy on 16 Oct 2020. Please confirm and update accordingly.' answered with 'Concomitant procedures page has been updated accordingly.' (Site from CRA).	Blessing Felix-Okoroji (b) (4)	03 Nov 2020 14:42:03
User opened query 'Please update the concomitant procedures page. Per source, it states that the subject had a prostate biopsy on 16 Oct 2020. Please confirm and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	02 Nov 2020 22:38:53
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES, ATC: POSTERIOR PITUITARY LOBE HORMONES, ATC: VASOPRESSIN AND ANALOGUES, PRODUCT: DESMOPRESSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 23:58:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 23:58:16
Data point term sent to Coder	System	13 Oct 2020 20:25:38
User entered 'Desmopressin'	(b) (4), (b) (6)	13 Oct 2020 20:24:50

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:56:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 20:24:50

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:56:38

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'Urinary Incontinence'	(b) (4), (b) (6)	13 Oct 2020 20:24:50

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:56:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered '0.2'	(b) (4), (b) (6)	13 Oct 2020 20:24:50

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:56:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Oct 2020 20:24:50

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:56:38

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:24:50

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:56:38

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'other (OTHER)'	(b) (4), (b) (6)	13 Oct 2020 20:24:50

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:56:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'one tablet 2-3 times a week'	(b) (4), (b) (6)	13 Oct 2020 20:24:50

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:56:38

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Oct 2020 20:24:50

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:56:38

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:24:50

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:56:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered '6 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 20:24:50

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:56:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 20:24:50

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:56:38

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:24:50

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:56:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:24:50

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:56:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:36:49
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 20:24:50

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:56:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 20:24:50

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:56:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 20:24:50

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 10:56:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 20:24:50

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:56:38

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 21:41:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 21:41:41
Data point term sent to Coder	System	10 Nov 2020 21:24:44
User entered 'omeprazole'	Elisa Moralez (b) (4)	10 Nov 2020 21:24:29

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:56:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:24:29

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:56:38

[Indication](#)

Audit	User	Time (GMT)
User entered 'omeprazole'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:24:29

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:56:38

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '40'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:24:29

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:56:38

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:24:29

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:56:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:24:29

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:56:38

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:24:29

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:56:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:24:29

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:56:38

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:24:29

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:56:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:24:29

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:56:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '04 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:24:29

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:56:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:24:29

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:56:38

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:24:29

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:56:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:24:29

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:56:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:24:29

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:56:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	10 Nov 2020 21:24:29

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:56:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 21:24:29

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 10:56:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Nov 2020 21:24:29

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:38

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: CIPROFLOXACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 02:32:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 02:32:46
Data point term sent to Coder	System	10 Nov 2020 21:25:46
User entered 'ciprofloxacin'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:06

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:06

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:38

[Indication](#)

Audit	User	Time (GMT)
User entered 'lower urinary tract symptoms'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:06

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:38

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '500'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:06

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:38

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:06

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:06

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:38

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:06

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:06

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:38

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:06

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:06

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:06

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:06

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:38

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:06

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '02 Oct 2020'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:06

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:06

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	10 Nov 2020 21:25:06

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 21:25:06

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 10:56:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Nov 2020 21:25:06

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:56:38

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Nov 2020 14:58:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Nov 2020 14:58:32
Data point term sent to Coder	System	10 Nov 2020 21:26:49
User entered 'metronidazole'	Elisa Moralez (b) (4)	10 Nov 2020 21:25:50
	(b) (4)	

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:56:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:50

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:56:38

[Indication](#)

Audit	User	Time (GMT)
User entered 'lower urinary tract symptoms'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:50

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:56:38

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '500'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:50

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:56:38

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:50

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:56:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:50

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:56:38

[Frequency](#)

Audit	User	Time (GMT)
User entered 'three times daily (TID)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:50

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:56:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:50

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:56:38

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:50

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:56:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:50

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:56:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:50

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:56:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:50

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:56:38

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:50

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:56:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '02 Oct 2020'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:50

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:56:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:25:50

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:56:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	10 Nov 2020 21:25:50

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:56:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 21:25:50

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 10:56:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Nov 2020 21:25:50

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:56:38

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: OTHER ANTIHYPERTENSIVES, ATC: ANTIHYPERTENSIVES FOR PULMONARY ARTERIAL HYPERTENSION, PRODUCT: SILDENAFIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 21:27:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 21:27:40
Data point term sent to Coder	System	10 Nov 2020 21:26:49
User entered 'Sildenafil'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:26:26

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:56:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:26:26

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:56:38

[Indication](#)

Audit	User	Time (GMT)
User entered 'pulmonary hypertension'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:26:26

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:56:38

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '20'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:26:26

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:56:38

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:26:26

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:56:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:26:26

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:56:38

[Frequency](#)

Audit	User	Time (GMT)
User entered 'three times daily (TID)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:26:26

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:56:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:26:26

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:56:38

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:26:26

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:56:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:26:26

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:56:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '19 Nov 2019' reason for change: New Information	Frances Saubon (b) (4) (b) (4)	13 Nov 2020 18:56:47
User entered '16 Oct 2020'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:26:26

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:56:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:26:26

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:56:38

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:26:26

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:56:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:26:26

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:56:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:26:26

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:56:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	10 Nov 2020 21:26:26

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:56:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 21:26:26

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 10:56:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Nov 2020 21:26:26

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:56:38

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS USED IN ERECTILE DYSFUNCTION, PRODUCT: SILDENAFIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 21:28:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 21:28:42
Data point term sent to Coder	System	10 Nov 2020 21:27:50
User entered 'Sildenafil'	Elisa Moralez (b) (4)	10 Nov 2020 21:27:01
	(b) (4)	

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:56:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:01

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:56:38

[Indication](#)

Audit	User	Time (GMT)
User entered 'erectile dysfunction'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:01

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:56:38

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '100'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:01

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:56:38

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:01

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:56:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:01

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:56:38

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:01

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:56:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:01

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:56:38

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:01

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:56:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:01

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:56:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 1998'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:01

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:56:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:01

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:56:38

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:01

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:56:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:01

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:56:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:01

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:56:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:27:01

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:56:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:27:01

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 10:56:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:27:01

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:56:38

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: AMINOGLYCOSIDE ANTIBACTERIALS, ATC: OTHER AMINOGLYCOSIDES, PRODUCT: GENTAMICIN SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 03:51:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 03:51:44
Data point term sent to Coder	System	10 Nov 2020 21:27:50
User entered 'gentamicin sulfate'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:40

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:56:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:40

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:56:38

[Indication](#)

Audit	User	Time (GMT)
User entered 'lower urinary tract symptoms'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:40

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:56:38

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '80'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:40

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:56:38

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:40

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:56:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:40

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:56:38

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:40

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:56:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:40

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:56:38

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intravenous (INTRAVENOUS)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:40

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:56:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:40

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:56:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:40

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:56:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:40

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:56:38

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:40

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:56:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:40

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:56:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	10 Nov 2020 21:27:40

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:56:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:27:40

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:56:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:27:40

US3322353

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 10:56:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:27:40

US3322353

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 10:56:38

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	03 Nov 2020 14:40:25

US3322353

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 10:56:38

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Oct 2020'	Blessing Felix-Okoroji (b) (4)	03 Nov 2020 14:40:57

US3322353

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 10:56:38

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'Prostate Biopsy'	Blessing Felix-Okoroji (b) (4)	03 Nov 2020 14:40:57

US3322353

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 10:56:38

[Indication](#)

Audit	User	Time (GMT)
User entered 'Diagnostic (DIAGNOSTIC)'	Blessing Felix-Okoroji (b) (4)	03 Nov 2020 14:40:57

US3322353

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 10:56:38

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Blessing Felix-Okoroji (b) (4)	03 Nov 2020 14:40:57

US3322353

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 10:56:38

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '25 Sep 2020'	Frances Saubon (b) (4) (b) (4)	16 Nov 2020 15:39:37

US3322353

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 10:56:38

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'Prostate Magnetic Resonance Imaging with or with out contrast'	Frances Saubon (b) (4) (b) (4)	16 Nov 2020 15:39:37

US3322353

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 10:56:38

[Indication](#)

Audit	User	Time (GMT)
User entered 'Diagnostic (DIAGNOSTIC)'	Frances Saubon (b) (4) (b) (4)	16 Nov 2020 15:39:37

US3322353

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 10:56:38

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Frances Saubon (b) (4) (b) (4)	16 Nov 2020 15:39:37

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:38

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'USA-US060-2020-MRNA-1273-P301000007'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:38

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'Yes (Y)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:38

Death

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'No (N)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:38

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'No (N)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'No (N)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'No (N)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'No (N)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:38

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'Yes (Y)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'Veronica'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'Fragoso'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:38

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered '6550 Mapleridge Street'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:38

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'Houston'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:38

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'TX'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:38

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered '77081'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:38

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:20:53
User entered 'US'	System	29 Oct 2020 13:46:20

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	16 Nov 2020 14:21:03
User entered '1'	System	29 Oct 2020 13:46:20

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:38

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'USA-US060-2020-MRNA-1273-P301000007'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:38

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'Yes (Y)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:38

Death

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'No (N)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:38

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'No (N)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'No (N)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'No (N)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'No (N)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:38

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'Yes (Y)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:38

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'Veronica'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:38

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'Fragoso'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:38

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered '6550 Mapleridge Street'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:38

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'Houston'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:38

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'TX'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:38

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered '77081'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:38

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:20:53
User entered 'US'	System	29 Oct 2020 13:46:20

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	16 Nov 2020 14:21:03
User entered '1'	System	29 Oct 2020 13:46:20

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:56:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '29/Oct/2020 13:46'	System	29 Oct 2020 13:46:20

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 10:56:38

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:20:53
User entered 'I'	(b) (4), (b) (6)	29 Oct 2020 13:46:20

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:38

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'USA-US060-2020-MRNA-1273-P301000007'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:38

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'Yes (Y)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:38

Death

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'No (N)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:38

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'No (N)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'No (N)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'No (N)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'No (N)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

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[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'Yes (Y)'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

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[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'Veronica'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'Fragoso'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:38

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered '6550 Mapleridge Street'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

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[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'Houston'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:38

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered 'TX'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:38

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 13:46:14
User entered '77081'	System	29 Oct 2020 13:44:21

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:38

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:20:53
User entered 'US'	System	29 Oct 2020 13:46:20

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 26 Nov 2020 10:56:38

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	16 Nov 2020 14:21:03
User entered '1'	System	29 Oct 2020 13:46:20

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:56:38

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '16/Nov/2020 09:21'	System	16 Nov 2020 14:21:03

US3322353

Folder: SAE USA-US060-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 10:56:38

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	16 Nov 2020 14:21:03