

US3752153 (Prod: Baptist Health Center for Clinical Research)

Generated By: KC Joubran

Generated On: 26 Nov 2020 11:15:20

All time stamps listed in this document are displayed in GMT

US3752153

Form: Participant Creation

Generated On: 26 Nov 2020 11:15:20

[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 11:15:20

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

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:20

Date of Birth (MMM yyyy)	(b) (6) 1949
Age	71
Age Units	YEARS
Age (Derived)	71
Sex	Female ☒ Male ☐
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:20

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:15:20

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:15:20

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:20

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

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:15:20

Condition	HEARING LOSS
Start date (dd MMM yyyy)	UN UNK 1980
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1980
Start Year (derived)	1980
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:15:20

Condition	TINNITUS
Start date (dd MMM yyyy)	UN UNK 1980
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1980
Start Year (derived)	1980
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:15:20

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
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 (5)

Generated On: 26 Nov 2020 11:15:20

Condition	TOTAL HYSTERECTOMY (ASSOCIATED CONDITION UNKNOWN)
Start date (dd MMM yyyy)	UN UNK 1994
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1994
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1994
Start Year (derived)	1994
Stop Month and Year (derived)	JAN 1994
Stop Year (derived)	1994

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:15:20

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

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:15:20

Condition	PSORIASIS
Start date (dd MMM yyyy)	UN UNK 1985
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1985
Start Year (derived)	1985
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:15:20

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

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:15:20

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

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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:15:20

Condition	MENIERE'S DISEASE
Start date (dd MMM yyyy)	UN UNK 1980
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1980
Start Year (derived)	1980
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:15:20

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

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Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:15:20

Condition	OBSTRUCTIVE SLEEP APNEA
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:15:20

Condition	PILONIDAL CYST REMOVAL
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1990
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	JAN 1990
Stop Year (derived)	1990

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Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:15:20

Condition	BONE SPUR SURGERY
Start date (dd MMM yyyy)	UN UNK 2004
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2004
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2004
Start Year (derived)	2004
Stop Month and Year (derived)	JAN 2004
Stop Year (derived)	2004

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Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:15:20

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

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:20

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	19 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	11:25 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 11:25
Height (<i>xxx.x</i>)	63.0 in
Weight (<i>xxx.x</i>)	220.2 lb
BMI (<i>xxx.x</i>)	39.08824 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:20

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:15:20

Date of assessment (<i>dd MMM yyyy</i>)	19 AUG 2020
Is the participant of childbearing potential?	Yes ☐
	No ☒
If No, what is the reason?	Surgically sterile ☒
	Post-menopausal ☐
	Partner medically sterile ☐
	Not reached age of Menarche ☐
	Other ☐
If Partner medically sterile or Other, specify	
If Surgically sterile, date of surgery (<i>dd MMM yyyy</i>)	UN UNK 1994
Date of surgery unknown	False
If Post-menopausal, date of last menstruation (<i>dd MMM yyyy</i>)	
Date of last menstruation unknown	False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:20

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify RETIRED

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:20

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	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:15:20

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

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:20

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

What was the participant's randomization number? 187017

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:15:20

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:20

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	19 AUG 2020
Time of assessment (00:00-23:59)	11:25 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 11:25
Temperature (xxx.x)	098.1 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	069 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	080 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:20

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	19 AUG 2020
Time of assessment (00:00-23:59)	13:15 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 13:15
Temperature (xxx.x)	98.1 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:20

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:20

Was study treatment given?	Yes ☒
	No ☐
If No, reason not given	Participant declined due to Adverse Event ☐
	Physician withheld dose due to Adverse Event ☐
	Death ☐
	Lost To Follow-Up ☐
	Physician Decision ☐
	Pregnancy ☐
	Protocol Deviation ☐
	Study Terminated by Sponsor ☐
	Withdrawal of Consent by Participant ☐
	Confirmed COVID-19 ☐
	Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? (dd MMM yyyy)	19 AUG 2020
What was the treatment time? (00:00-23:59)	12:44 (24 HR)
Treatment Date and Time (derived)	19 AUG 2020 12:44
Which arm was used to give treatment?	Left Arm ☒
	Right Arm ☐
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:20

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

19 AUG 2020

Collection time (*00:00-23:59*)

11:56 (24 HR)

Collection date and time (derived)

19 AUG 2020 11:56

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:15:20

Collection date (<i>dd MMM yyyy</i>)			19 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:54	19 AUG 2020 11:54
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:15:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

19 AUG 2020 13:08

PC Open Date & Time

19 AUG 2020 13:04

PC Close Date & Time

19 AUG 2020 15:34

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

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 96.6 °F

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

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

PC Time Stamp	19 AUG 2020 20:46
PC Open Date & Time	19 AUG 2020 16:29
PC Close Date & Time	20 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:20

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

95.9 °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

20 AUG 2020 19:52

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:20

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

95.5 °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

21 AUG 2020 18:47

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:15:20

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

95.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 18:53

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:15:20

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

97.1 °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

23 AUG 2020 19:05

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:15:20

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

94.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 20:18

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:15:20

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

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp 25 AUG 2020 19:31

PC Open Date & Time 25 AUG 2020 12:00

PC Close Date & Time 26 AUG 2020 11:59

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 AUG 2020 13:10

PC Open Date & Time

19 AUG 2020 13:04

PC Close Date & Time

19 AUG 2020 15:34

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

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

19 AUG 2020 20:47

PC Open Date & Time

19 AUG 2020 16:29

PC Close Date & Time

20 AUG 2020 11:59

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 19:53

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 AUG 2020 18:47

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 AUG 2020 18:53

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 AUG 2020 19:06

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 AUG 2020 20:19

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 19:31

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

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 ☐

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

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

No ☒

Yes ☐

PC Time stamp	19 AUG 2020 13:10
PC Open Date & Time	19 AUG 2020 13:04
PC Close Date & Time	19 AUG 2020 15:34

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

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 ☐

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

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

No ☒

Yes ☐

PC Time stamp	19 AUG 2020 20:48
PC Open Date & Time	19 AUG 2020 16:29
PC Close Date & Time	20 AUG 2020 11:59

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:20

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 ☒

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:20

Yes ☐	
PC Time stamp	20 AUG 2020 19:54
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:20

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 ☒

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:20

Yes ☐	
PC Time stamp	21 AUG 2020 18:48
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:20

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 ☒

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:20

Yes ☐	
PC Time stamp	22 AUG 2020 18:54
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:20

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 ☒

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:20

Yes ☐	
PC Time stamp	23 AUG 2020 19:06
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:20

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 ☒

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:20

Yes ☐	
PC Time stamp	24 AUG 2020 20:20
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:20

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 ☒

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:20

Yes ☐	
PC Time stamp	25 AUG 2020 19:32
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3752153

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752153

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752153

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752153

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752153

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752153

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752153

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:20

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	16 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3752153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:20

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	16 SEP 2020
Time of assessment (00:00-23:59)	09:05 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 09:05
Temperature (xxx.x)	98.1 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3752153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:20

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	16 SEP 2020
Time of assessment (00:00-23:59)	09:55 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 09:55
Temperature (xxx.x)	98.2 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3752153

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:20

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 SEP 2020

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

US3752153

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:20

Was study treatment given?	Yes ☒
	No ☐
If No, reason not given	Participant declined due to Adverse Event ☐
	Physician withheld dose due to Adverse Event ☐
	Death ☐
	Lost To Follow-Up ☐
	Physician Decision ☐
	Pregnancy ☐
	Protocol Deviation ☐
	Study Terminated by Sponsor ☐
	Withdrawal of Consent by Participant ☐
	Confirmed COVID-19 ☐
	Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? (dd MMM yyyy)	16 SEP 2020
What was the treatment time? (00:00-23:59)	09:35 (24 HR)
Treatment Date and Time (derived)	16 SEP 2020 09:35
Which arm was used to give treatment?	Left Arm ☒
	Right Arm ☐
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

US3752153

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:20

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	16 SEP 2020
Collection time (<i>00:00-23:59</i>)	09:22 (24 HR)
Collection date and time (derived)	16 SEP 2020 09:22

US3752153

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:15:20

Collection date (dd MMM yyyy)			16 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:20	16 SEP 2020 09:20
Nasopharyngeal Swab 2	No		

US3752153

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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 16 SEP 2020 10:01

PC Open Date & Time 16 SEP 2020 09:55

PC Close Date & Time 16 SEP 2020 12:25

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp 16 SEP 2020 20:24

PC Open Date & Time 16 SEP 2020 13:20

PC Close Date & Time 17 SEP 2020 11:59

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:20

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

98.5 °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

17 SEP 2020 16:17

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:20

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

97.1 °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

18 SEP 2020 19:41

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:15:20

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

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 20:59

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:15:20

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

95.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 20:30

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:15:20

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**

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 21 SEP 2020 12:00

PC Close Date & Time 22 SEP 2020 11:59

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:15:20

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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 20:49

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

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

16 SEP 2020 10:01

PC Open Date & Time

16 SEP 2020 09:55

PC Close Date & Time

16 SEP 2020 12:25

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

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 20:25

PC Open Date & Time

16 SEP 2020 13:20

PC Close Date & Time

17 SEP 2020 11:59

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:20

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 ☐

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

6

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

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

Yes ☒

No ☐

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

6

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 16:21

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

8

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

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

Yes ☒

No ☐

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

8

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 19:43

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:20

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 ☐

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

6

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

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

Yes ☒

No ☐

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

6

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 21:00

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:20

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 ☐

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

6

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

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

Yes ☒

No ☐

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

6

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 SEP 2020 20:31

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:20

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:20

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 ☐

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

6

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

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

Yes ☒

No ☐

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

6

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 20:49

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

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 ☐

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 10:02
PC Open Date & Time	16 SEP 2020 09:55
PC Close Date & Time	16 SEP 2020 12:25

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

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 ☐

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 20:26
PC Open Date & Time	16 SEP 2020 13:20
PC Close Date & Time	17 SEP 2020 11:59

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:20

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 ☒

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:20

Yes ☐	
PC Time stamp	17 SEP 2020 16:22
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:20

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 ☐

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:20

		Yes ☐
PC Time stamp		
PC Open Date & Time		18 SEP 2020 12:00
PC Close Date & Time		19 SEP 2020 11:59

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:20

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 ☒

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:20

Yes ☐	
PC Time stamp	19 SEP 2020 21:01
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:20

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 ☒

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:20

Yes ☐	
PC Time stamp	20 SEP 2020 20:31
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:20

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 ☐

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:20

		Yes ☐
PC Time stamp		
PC Open Date & Time		21 SEP 2020 12:00
PC Close Date & Time		22 SEP 2020 11:59

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:20

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 ☒

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:20

Yes ☐	
PC Time stamp	22 SEP 2020 20:50
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

DAY 8

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 ☐

PC Time Stamp

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(9)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

DAY 9

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 ☐

PC Time Stamp

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3752153

Folder: Diary Dose 2 (1)

Form: Redness_Day(8)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

DAY 8

Is there any REDNESS AT INJECTION SITE?

Yes ☐

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

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

PC Time Stamp

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3752153

Folder: Diary Dose 2 (1)

Form: Redness_Day(9)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

DAY 9

Is there any REDNESS AT INJECTION SITE?

Yes ☐

No ☐

Please record - REDNESS AT INJECTION SITE (in mm)

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

PC Time Stamp

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3752153

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

DAY 8

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

Yes ☐

No ☐

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

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

PC Time stamp

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3752153

Folder: Diary Dose 2 (1)

Form: Swelling_Day(9)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

DAY 9

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

Yes ☐

No ☐

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

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

PC Time stamp

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3752153

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☐
	Yes ☐
PC Time stamp	
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3752153

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☐
	Yes ☐
PC Time stamp	
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3752153

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752153

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752153

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752153

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752153

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752153

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752153

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:20

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	12 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3752153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:20

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	12 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	11:35 (24 HR)
Vital Signs Date and Time (derived)	12 OCT 2020 11:35
Temperature (<i>xxx.x</i>)	98.3 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	67 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3752153

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:20

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 OCT 2020

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

US3752153

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:20

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

12 OCT 2020

Collection time (*00:00-23:59*)

11:42 (24 HR)

Collection date and time (derived)

12 OCT 2020 11:42

US3752153

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3752153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 OCT 2020 13:50:07

Patient Cloud Open Date & Time

19 OCT 2020 00:01

Patient Cloud Close Date & Time

23 OCT 2020 23:59

US3752153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 OCT 2020 08:07:52

Patient Cloud Open Date & Time

26 OCT 2020 00:01

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2020 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2020 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2020 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2020 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2020 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

[Patient Cloud Close Date & Time](#)

24 NOV 2020 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

DAY 103

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2020 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2020 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

15 DEC 2020 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2020 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

DAY 131

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2020 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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 ☐

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2021 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

DAY 145

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2021 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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 ☐

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2021 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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 ☐

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2021 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

DAY 166

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2021 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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 ☐

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 FEB 2021 00:01

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09 FEB 2021 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2021 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2021 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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 ☐

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2021 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2021 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2021 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2021 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

DAY 222

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2021 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

DAY 229

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2021 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2021 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

DAY 243

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2021 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2021 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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 ☐

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2021 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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 ☐

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

DAY 285

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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 ☐

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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 ☐

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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 ☐

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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 ☐

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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 ☐

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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 ☐

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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 ☐

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2021 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

DAY 446

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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 ☐

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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 ☐

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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 ☐

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

14 DEC 2021 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

DAY 488

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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 ☐

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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 ☐

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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 ☐

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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 ☐

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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 ☐

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

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22 FEB 2022 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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 ☐

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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 ☐

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

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08 MAR 2022 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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 ☐

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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 ☐

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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 ☐

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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 ☐

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

DAY 614

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

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03 MAY 2022 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

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10 MAY 2022 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

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17 MAY 2022 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

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24 MAY 2022 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

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31 MAY 2022 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

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07 JUN 2022 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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 ☐

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

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14 JUN 2022 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

DAY 670

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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 ☐

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

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28 JUN 2022 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

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05 JUL 2022 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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12 JUL 2022 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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 ☐

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

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15 JUL 2022 00:01

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19 JUL 2022 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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 ☐

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2022 00:01

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26 JUL 2022 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

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02 AUG 2022 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 AUG 2022 00:01

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16 AUG 2022 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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 ☐

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

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23 AUG 2022 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

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30 AUG 2022 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

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06 SEP 2022 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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 ☐

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

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09 SEP 2022 00:01

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13 SEP 2022 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

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20 SEP 2022 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT	DAY 775
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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 ☐

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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 ☐

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 OCT 2022 00:01

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18 OCT 2022 23:59

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

DAY 796

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2022 23:59

US3752153

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3752153

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:20

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

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Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:20

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

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Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:15:20

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

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Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:15:20

Generate Next COVID-19 Assessment

Yes ☐

No ☐

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:15:20

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:20

AEID	
Adverse event	LEFT ARM INJECTION SITE SWELLING
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)	17 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)	25 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:20

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

US3752153

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:20

AEID	
Adverse event	LEFT ARM INJECTION SITE PAIN
Was this a medically-attended AE?	Yes ☐ No ☒
Was this a Solicited Adverse Reaction?	Yes ☒ No ☐
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	17 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)	25 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:20

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

US3752153

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:20

AEID	
Adverse event	LEFT ARM INJECTION SITE INDURATION
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)	17 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)	25 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:20

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

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:20

AEID	
Adverse event	LEFT ARM INJECTION SITE REDNESS (TYPE OF REDNESS UNKNOWN AND UNKNOWN IF URTICARIAL OR NONURTICARIAL)
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)	17 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)	25 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:20

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

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:20

AEID	
Adverse event	WORSENING OF OSTEOARTHRITIS (UNKNOWN LOCATION)
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)	20 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	29 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:20

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

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:20

AEID	USA-US113-2020-MRNA-1273-P30 1000012
Adverse event	TOTAL RIGHT KNEE ARTHROPLASTY REQUIRING HOSPITALIZATION
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)	10 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	10 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☒
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	10 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	11 NOV 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:20

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT HAD A TOTAL RIGHT KNEE ARTHROPLASTY THAT REQUIRED AN ADMISSION TO THE HOSPITAL
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:15:20

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

Yes ☒

No ☐

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

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:20

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:20

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 1990
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:20

Name of Medication	BUPROPION
Prophylaxis	Yes ☐ No ☒
Indication	DEPRESSION
Dose per administration	150
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☐ twice daily ☒ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:20

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2009
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:20

Name of Medication	CBD OIL
Prophylaxis	Yes ☐ No ☒
Indication	OSTEOARTHRITIS
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	APPLICATION
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☒ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:20

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:20

Name of Medication	IBUPROFEN
Prophylaxis	Yes ☐ No ☒
Indication	OSTEOARTHRITIS
Dose per administration	200
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☒ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:20

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☐
Vaginal	☐
Rectal	☐
Intravenous	☐
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☐
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	31 AUG 2020
Start date completely unknown	False
Ongoing?	Yes ☒
	No ☐
If not Ongoing, End date (dd MMM yyyy) _____	
Was this medication taken for solicited event?	Yes ☐
	No ☒
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:20

Name of Medication	ANNUAL FLU VACCINATION
Prophylaxis	Yes ☒ No ☐
Indication	PROPHYLAXIS FOR INFLUENZA
Dose per administration	0.5
Dose unit	mg ☐ ug ☐ mL ☒ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☒ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:20

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

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:20

Name of Medication	PNEUMONIA VACCINE
Prophylaxis	Yes ☒ No ☐
Indication	PNEUMONIA PREVENTION
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	INJECTION
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☒ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☒

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:20

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

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:20

Name of Medication	IBUPROFEN
Prophylaxis	Yes ☐ No ☒
Indication	LEFT ARM INJECTION SITE PAIN RELIEF
Dose per administration	150
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:20

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		17 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		25 SEP 2020
Was this medication taken for solicited event?	Yes	☒
	No	☐
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:20

Name of Medication	IBUPROFEN
Prophylaxis	Yes ☐ No ☒
Indication	TREAT KNEE PAIN
Dose per administration	600
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:20

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	25 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy)		25 AUG 2020
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:20

Name of Medication	ATORVASTATIN
Prophylaxis	Yes ☐ No ☒
Indication	MIXED HYPERLIPIDEMIA
Dose per administration	10
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:20

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

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:20

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

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:20

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

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:15:20

Name of Medication FLUTICASONE FUROATE-VILANTEROL (BREO-ELLIPTA)

Prophylaxis Yes ☐ No ☒

Indication ASTHMA

Dose per administration 100/25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:15:20

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

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:15:20

Name of Medication	OXYCODONE/ACETAMINOPHE N
Prophylaxis	Yes ☐ No ☒
Indication	POST PROCEDURE PAIN
Dose per administration	7.5/325
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:15:20

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

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:15:20

Name of Medication	ALBUTEROL ACTUATION INHALER
Prophylaxis	Yes ☐ No ☒
Indication	ASTHMA
Dose per administration	90
Dose unit	mg ☐ ug ☒ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:15:20

	Intramuscular	☐
	Respiratory (Inhalation)	☒
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 JAN 2020
Start date completely unknown		False
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3752153

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:15:20

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3752153

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 11:15:20

Procedure/Surgery date (<i>dd MMM yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
21 OCT 2020	CT RIGHT KNEE WITHOUT CONTRAST	Diagnostic	
10 NOV 2020	MAKO RIGHT TOTAL KNEE ARTHROPLASTY	Adverse Event	

US3752153

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:15:20

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

US3752153

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:15:20

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 ☐

US3752153

Folder: SAE USA-US113-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:20

SAEID	USA-US113-2020-MRNA-1273-P301000012
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	PRIYANTHA
Investigator's Last Name	WIJEWARDANE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3752153

Folder: SAE USA-US113-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:15:20

SAEID	USA-US113-2020-MRNA-1273-P301000012
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	PRIYANTHA
Investigator's Last Name	WIJEWARDANE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	13/NOV/2020 14:50
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

US3752153 (Prod: Baptist Health Center for Clinical Research)

US3752153

Form: Participant Creation

Generated On: 26 Nov 2020 11:15:20

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3752153'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	19 Aug 2020 16:19:25

US3752153

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:15:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 17:53:54

US3752153

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered '19 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	19 Aug 2020 16:19:27

US3752153

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	19 Aug 2020 17:53:54

US3752153

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:15:20

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	19 Aug 2020 17:53:54

US3752153

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:20

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1949'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	19 Aug 2020 16:19:28

US3752153

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:20

[Age](#)

Audit	User	Time (GMT)
User entered '71'	(b) (4), (b) (6)	19 Aug 2020 21:06:37

US3752153

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:20

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	19 Aug 2020 21:06:37

US3752153

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:20

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '71'	System	19 Aug 2020 17:54:15

US3752153

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:20

[Sex](#)

Audit	User	Time (GMT)
User entered 'Female (F)'	(b) (4), (b) (6)	19 Aug 2020 21:06:37

US3752153

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:20

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	19 Aug 2020 21:06:37

US3752153

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:20

[White](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	19 Aug 2020 21:06:37

US3752153

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:20

[Black](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 21:06:37

US3752153

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:20

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 21:06:37

US3752153

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:20

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 21:06:37

US3752153

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:20

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 21:06:37

US3752153

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:20

[Other](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 21:06:37

US3752153

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:20

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 21:06:37

US3752153

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:20

[Unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 21:06:37

US3752153

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:15:20

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 21:06:37

US3752153

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered '19 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 17:54:15

US3752153

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	19 Aug 2020 17:54:15

US3752153

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered '2020'	System	19 Aug 2020 17:54:15

US3752153

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:20

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 2 (2)'	(b) (4), (b) (6)	19 Aug 2020 17:54:15

US3752153

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 17:54:15

US3752153

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 17:54:15

US3752153

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:20

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 17:54:15

US3752153

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:20

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 17:54:15

US3752153

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:20

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	19 Aug 2020 16:19:27

US3752153

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:15:20

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 17:54:21

US3752153

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 17:54:21

US3752153

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:15:20

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 21:07:05

US3752153

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:20

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Cataract operation, LLT: Cataract operation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 21:08:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 21:08:12
Data point term sent to Coder	System	19 Aug 2020 21:07:46
User entered 'Cataract surgery'	(b) (4), (b) (6) (b) (4)	19 Aug 2020 21:07:33

US3752153

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	(b) (4), (b) (6)	19 Aug 2020 21:07:33

US3752153

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 21:07:33

US3752153

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 21:07:33

US3752153

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	(b) (4), (b) (6)	19 Aug 2020 21:07:33

US3752153

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 21:07:33

US3752153

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	19 Aug 2020 21:07:33

US3752153

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered '2015'	System	19 Aug 2020 21:07:33

US3752153

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	19 Aug 2020 21:07:33

US3752153

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered '2015'	System	19 Aug 2020 21:07:33

US3752153

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:15:20

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Hearing disorders, HLT: Hearing losses, PT: Deafness, LLT: Hearing loss - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 21:10:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 21:10:08
Data point term sent to Coder	System	19 Aug 2020 21:08:46
User entered 'Hearing loss'	(b) (4), (b) (6) (b) (4)	19 Aug 2020 21:07:56

US3752153

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered 'un UNK 1980'	(b) (4), (b) (6)	19 Aug 2020 21:07:56

US3752153

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:15:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 21:07:56

US3752153

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:15:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 20:16:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Sep 2020 20:16:42
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 20:16:42
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 21:07:56
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 21:07:56

US3752153

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 21:07:56

US3752153

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:15:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 21:07:56

US3752153

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered 'Jan 1980'	System	19 Aug 2020 21:07:56

US3752153

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered '1980'	System	19 Aug 2020 21:07:56

US3752153

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:07:56

US3752153

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:07:56

US3752153

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:15:20

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Inner ear and VIIIth cranial nerve disorders, HLT: Inner ear signs and symptoms, PT: Tinnitus, LLT: Tinnitus - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 21:10:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 21:10:08
Data point term sent to Coder	System	19 Aug 2020 21:08:46
User entered 'Tinnitus'	(b) (4), (b) (6)	19 Aug 2020 21:08:22

US3752153

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered 'un UNK 1980'	(b) (4), (b) (6)	19 Aug 2020 21:08:22

US3752153

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:15:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 21:08:22

US3752153

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:15:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 21:08:22

US3752153

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 21:08:22

US3752153

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:15:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 21:08:22

US3752153

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered 'Jan 1980'	System	19 Aug 2020 21:08:22

US3752153

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered '1980'	System	19 Aug 2020 21:08:22

US3752153

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:08:22

US3752153

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:08:22

US3752153

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:15:20

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 21:10:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 21:10:09
Data point term sent to Coder	System	19 Aug 2020 21:09:47
User entered 'Hypercholesterolemia'	(b) (4), (b) (6)	19 Aug 2020 21:08:57

US3752153

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	(b) (4), (b) (6)	19 Aug 2020 21:08:57

US3752153

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:15:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 21:08:57

US3752153

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:15:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 21:08:57

US3752153

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 21:08:57

US3752153

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:15:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 21:08:57

US3752153

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	19 Aug 2020 21:08:57

US3752153

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered '2015'	System	19 Aug 2020 21:08:57

US3752153

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:08:57

US3752153

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:08:57

US3752153

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:15:20

Condition

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 15:22:05
User closed query 'Per DM CLR: Please review this procedure and verify if the subject is Surgically Sterile. If yes, please review Childbearing Potential eCRF page, as this information was not noted for this subject. Please reconcile and update applicable eCRFs as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 15:21:25
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Total hysterectomy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Oct 2020 21:20:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Oct 2020 21:20:29
Query 'Per DM CLR: Please review this procedure and verify if the subject is Surgically Sterile. If yes, please review Childbearing Potential eCRF page, as this information was not noted for this subject. Please reconcile and update applicable eCRFs as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 21:20:25
Data point term sent to Coder	System	12 Oct 2020 21:20:05
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 21:19:17
Coding entries removed.	(b) (4), (b) (6)	12 Oct 2020 21:19:09
User entered 'TOTAL HYSTERECTOMY (associated condition unknown)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 21:19:09
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 20:47:54

US3752153

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:15:20

[Condition](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review this procedure and verify if the subject is Surgically Sterile. If yes, please review Childbearing Potential eCRF page, as this information was not noted for this subject. Please reconcile and update applicable eCRFs as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 20:47:44
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Total hysterectomy - version MedDRA\23.0.	Coder Import (b) (4)	19 Aug 2020 21:10:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	19 Aug 2020 21:10:09
Data point term sent to Coder	System	19 Aug 2020 21:09:48
User entered 'Total hysterectomy'	(b) (4), (b) (6)	19 Aug 2020 21:09:29

US3752153

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered 'un UNK 1994'	(b) (4), (b) (6)	19 Aug 2020 21:09:29

US3752153

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:15:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 21:09:29

US3752153

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:15:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 21:09:29

US3752153

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered 'un UNK 1994'	(b) (4), (b) (6)	19 Aug 2020 21:09:29

US3752153

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:15:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 21:09:29

US3752153

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered 'Jan 1994'	System	19 Aug 2020 21:09:29

US3752153

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered '1994'	System	19 Aug 2020 21:09:29

US3752153

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered 'Jan 1994'	System	19 Aug 2020 21:09:29

US3752153

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered '1994'	System	19 Aug 2020 21:09:29

US3752153

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:15:20

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis NOS - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 14:58:02
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 14:58:02
Data point term sent to Coder	System	12 Oct 2020 21:18:01
Coding entries removed.	(b) (4), (b) (6)	12 Oct 2020 21:17:59
User entered 'OSTEOARTHRITIS (unknown site)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 21:17:59
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 21:12:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 21:12:10
Data point term sent to Coder	System	19 Aug 2020 21:10:51
User entered 'Osteoarthritis'	(b) (4), (b) (6)	19 Aug 2020 21:09:51

US3752153

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered 'un UNK 2010'	(b) (4), (b) (6)	19 Aug 2020 21:09:51

US3752153

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:15:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 21:09:51

US3752153

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:15:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 21:09:51

US3752153

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 21:09:51

US3752153

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:15:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 21:09:51

US3752153

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	19 Aug 2020 21:09:51

US3752153

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered '2010'	System	19 Aug 2020 21:09:51

US3752153

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:09:51

US3752153

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:09:51

US3752153

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:15:20

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Psoriatic conditions, PT: Psoriasis, LLT: Psoriasis - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 21:12:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 21:12:09
Data point term sent to Coder	System	19 Aug 2020 21:10:51
User entered 'Psoriasis'	(b) (4), (b) (6)	19 Aug 2020 21:10:09

US3752153

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered 'un UNK 1985'	(b) (4), (b) (6)	19 Aug 2020 21:10:09

US3752153

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:15:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 21:10:09

US3752153

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:15:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 21:10:09

US3752153

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 21:10:09

US3752153

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:15:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 21:10:09

US3752153

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered 'Jan 1985'	System	19 Aug 2020 21:10:09

US3752153

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered '1985'	System	19 Aug 2020 21:10:09

US3752153

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:10:09

US3752153

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:10:09

US3752153

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:15:20

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Rosaceas, PT: Rosacea, LLT: Rosacea - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 21:12:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 21:12:10
Data point term sent to Coder	System	19 Aug 2020 21:10:52
User entered 'Rosacea'	(b) (4), (b) (6)	19 Aug 2020 21:10:23

US3752153

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	(b) (4), (b) (6)	19 Aug 2020 21:10:23

US3752153

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:15:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 21:10:23

US3752153

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:15:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 21:10:23

US3752153

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 21:10:23

US3752153

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:15:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 21:10:23

US3752153

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	19 Aug 2020 21:10:23

US3752153

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered '2018'	System	19 Aug 2020 21:10:23

US3752153

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:10:23

US3752153

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:10:23

US3752153

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:15:20

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 21:12:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 21:12:10
Data point term sent to Coder	System	19 Aug 2020 21:10:55
User entered 'Depression'	(b) (4), (b) (6)	19 Aug 2020 21:10:46

US3752153

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered 'un UNK 1960'	(b) (4), (b) (6)	19 Aug 2020 21:10:46

US3752153

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:15:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 21:10:46

US3752153

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:15:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 21:10:46

US3752153

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 21:10:46

US3752153

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:15:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 21:10:46

US3752153

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered 'Jan 1960'	System	19 Aug 2020 21:10:46

US3752153

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered '1960'	System	19 Aug 2020 21:10:46

US3752153

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:10:46

US3752153

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:10:46

US3752153

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:15:20

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Inner ear and VIIIth cranial nerve disorders, HLT: Inner ear disorders NEC, PT: Meniere's disease, LLT: Meniere's disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 21:13:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 21:13:07
Data point term sent to Coder	System	19 Aug 2020 21:11:57
User entered 'Meniere's disease'	(b) (4), (b) (6) (b) (4)	19 Aug 2020 21:11:08

US3752153

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered 'un UNK 1980'	(b) (4), (b) (6)	19 Aug 2020 21:11:08

US3752153

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:15:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 21:11:08

US3752153

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:15:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 21:11:08

US3752153

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 21:11:08

US3752153

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:15:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 21:11:08

US3752153

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered 'Jan 1980'	System	19 Aug 2020 21:11:08

US3752153

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered '1980'	System	19 Aug 2020 21:11:08

US3752153

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:11:08

US3752153

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:11:08

US3752153

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:15:20

[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)	19 Aug 2020 21:12:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 21:12:10
Data point term sent to Coder	System	19 Aug 2020 21:11:55
User entered 'Urinary incontinence'	(b) (4), (b) (6) (b) (4)	19 Aug 2020 21:11:28

US3752153

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	(b) (4), (b) (6)	19 Aug 2020 21:11:28

US3752153

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:15:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 21:11:28

US3752153

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:15:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 21:11:28

US3752153

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 21:11:28

US3752153

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:15:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 21:11:28

US3752153

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	19 Aug 2020 21:11:28

US3752153

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered '2018'	System	19 Aug 2020 21:11:28

US3752153

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:11:28

US3752153

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:11:28

US3752153

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:15:20

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Obstructive sleep apnea syndrome - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 21:14:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 21:14:12
Data point term sent to Coder	System	19 Aug 2020 21:12:59
User entered 'Obstructive sleep apnea'	(b) (4), (b) (6) (b) (4)	19 Aug 2020 21:12:11

US3752153

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered 'un UNK 1990'	(b) (4), (b) (6)	19 Aug 2020 21:12:11

US3752153

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:15:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 21:12:11

US3752153

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:15:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 21:12:11

US3752153

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 21:12:11

US3752153

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:15:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 21:12:11

US3752153

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered 'Jan 1990'	System	19 Aug 2020 21:12:11

US3752153

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered '1990'	System	19 Aug 2020 21:12:11

US3752153

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:12:11

US3752153

Folder: Screening

Form: Medical History (12)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:12:11

US3752153

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:15:20

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin and subcutaneous tissue therapeutic procedures NEC, PT: Pilonidal sinus repair, LLT: Pilonidal cyst excision - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 06:33:12
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	20 Aug 2020 06:33:12
Data point term sent to Coder	System	19 Aug 2020 21:13:04
User entered 'Pilonidal cyst removal'	(b) (4), (b) (6) (b) (4)	19 Aug 2020 21:12:50

US3752153

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered 'un UNK 1990'	(b) (4), (b) (6)	19 Aug 2020 21:12:50

US3752153

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:15:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 21:12:50

US3752153

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:15:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 21:12:50

US3752153

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered 'un UNK 1990'	(b) (4), (b) (6)	19 Aug 2020 21:12:50

US3752153

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:15:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 21:12:50

US3752153

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered 'Jan 1990'	System	19 Aug 2020 21:12:50

US3752153

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered '1990'	System	19 Aug 2020 21:12:50

US3752153

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered 'Jan 1990'	System	19 Aug 2020 21:12:50

US3752153

Folder: Screening

Form: Medical History (13)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered '1990'	System	19 Aug 2020 21:12:50

US3752153

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:15:20

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Bone therapeutic procedures NEC, PT: Bone lesion excision, LLT: Bone spur removal - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 21:15:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 21:15:08
Data point term sent to Coder	System	19 Aug 2020 21:14:11
User entered 'Bone spur surgery'	(b) (4), (b) (6)	19 Aug 2020 21:13:10

US3752153

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered 'un UNK 2004'	(b) (4), (b) (6)	19 Aug 2020 21:13:10

US3752153

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:15:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 21:13:10

US3752153

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:15:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 21:13:10

US3752153

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered 'un UNK 2004'	(b) (4), (b) (6)	19 Aug 2020 21:13:10

US3752153

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:15:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 21:13:10

US3752153

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered 'Jan 2004'	System	19 Aug 2020 21:13:10

US3752153

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered '2004'	System	19 Aug 2020 21:13:10

US3752153

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered 'Jan 2004'	System	19 Aug 2020 21:13:10

US3752153

Folder: Screening

Form: Medical History (14)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered '2004'	System	19 Aug 2020 21:13:10

US3752153

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:15:20

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 14:43:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 14:43:44
Data point term sent to Coder	System	13 Nov 2020 14:43:00
User entered 'Asthma'	Lauren Evans (b) (4) (b) (4)	13 Nov 2020 14:42:09

US3752153

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered empty.	Lauren Evans (b) (4) [REDACTED]	13 Nov 2020 14:42:09

US3752153

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:15:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '1'	Lauren Evans (b) (4) [REDACTED]	13 Nov 2020 14:42:09

US3752153

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:15:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lauren Evans (b) (4)	13 Nov 2020 14:42:09

US3752153

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered empty.	Lauren Evans (b) (4)	13 Nov 2020 14:42:09

US3752153

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:15:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Lauren Evans (b) (4) [REDACTED]	13 Nov 2020 14:42:09

US3752153

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 14:42:09

US3752153

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 14:42:09

US3752153

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 14:42:09

US3752153

Folder: Screening

Form: Medical History (16)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered empty.	System	13 Nov 2020 14:42:09

US3752153

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 21:14:15

US3752153

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered '19 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 21:14:15

US3752153

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered '11:25'	(b) (4), (b) (6)	19 Aug 2020 21:14:15

US3752153

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:25'	System	19 Aug 2020 21:14:15

US3752153

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered '63.0' in	(b) (4), (b) (6)	19 Aug 2020 21:14:15
DataPoint set to visible.	System	19 Aug 2020 17:54:21

US3752153

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered '220.2' lb	(b) (4), (b) (6)	19 Aug 2020 21:14:15
DataPoint set to visible.	System	19 Aug 2020 17:54:21

US3752153

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:20

BMI (xxx.x)

Audit	User	Time (GMT)
Amendment Manager: User entered '39.08824'	System	17 Sep 2020 00:14:09
User entered '39.1'	System	19 Aug 2020 21:14:15
DataPoint set to visible.	System	19 Aug 2020 17:54:21

US3752153

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:20

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	19 Aug 2020 21:14:15
DataPoint set to visible.	System	19 Aug 2020 17:54:21

US3752153

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:20

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 20:13:47
User entered '098.1' F	(b) (4), (b) (6)	19 Aug 2020 21:14:15

US3752153

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:20

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 20:13:47
User entered 'Oral (Oral)'	(b) (4), (b) (6)	19 Aug 2020 21:14:15

US3752153

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:20

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 21:14:15

US3752153

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 20:13:47
User entered '069'	(b) (4), (b) (6)	19 Aug 2020 21:14:15

US3752153

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:20

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	19 Aug 2020 21:14:15

US3752153

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 20:13:47
User entered '14'	(b) (4), (b) (6)	19 Aug 2020 21:14:15

US3752153

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	19 Aug 2020 21:14:15

US3752153

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 20:13:47
User entered '130'	(b) (4), (b) (6)	19 Aug 2020 21:14:15

US3752153

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Aug 2020 21:14:15

US3752153

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 20:13:47
User entered '080'	(b) (4), (b) (6)	19 Aug 2020 21:14:15

US3752153

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:20

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Aug 2020 21:14:15

US3752153

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 19:23:24
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 14:43:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 21:14:26

US3752153

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:20

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '19 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 19:23:24
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	17 Sep 2020 14:43:35
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 14:43:35
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	16 Sep 2020 14:40:01
User entered '19 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 21:14:26

US3752153

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered '19 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 21:15:59

US3752153

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 21:15:59

US3752153

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:15:20

[If No, what is the reason?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 04:54:52
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 15:09:29
User closed query 'Post-menopausal has not been entered, however date of last menstruation is provided, or Date of last menstruation unknown is checked. Please correct.' (Site from System).	System	05 Oct 2020 15:09:22
User opened query 'Post-menopausal has not been entered, however date of last menstruation is provided, or Date of last menstruation unknown is checked. Please correct.' (Site from System).	System	05 Oct 2020 15:06:08
User entered 'Surgically sterile (SURGICALLY STERILE)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 15:06:08
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Oct 2020 04:33:33
User closed query 'Surgically sterile has not been entered, however date of surgery is provided, or Date of surgery unknown is checked. Please correct.' (Site from System).	System	01 Sep 2020 21:14:40
User opened query 'Surgically sterile has not been entered, however date of surgery is provided, or Date of surgery unknown is checked. Please correct.' (Site from System).	System	01 Sep 2020 21:14:24
User closed query 'Post-menopausal has not been entered, however date of last menstruation is provided, or Date of last menstruation unknown is checked. Please correct.' (Site from System).	System	01 Sep 2020 21:14:24
User entered 'Post-menopausal (POST-MENOPAUSAL)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 21:14:24
User opened query 'Post-menopausal has not been entered, however date of last menstruation is provided, or Date of last menstruation unknown is checked. Please correct.' (Site from System).	System	01 Sep 2020 21:09:29

US3752153

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:15:20

If No, what is the reason?

Audit	User	Time (GMT)
User closed query 'Surgically sterile has not been entered, however date of surgery is provided, or Date of surgery unknown is checked. Please correct.' (Site from System).	System	01 Sep 2020 21:09:29
User entered 'Surgically sterile (SURGICALLY STERILE)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 21:09:29
User opened query 'Surgically sterile has not been entered, however date of surgery is provided, or Date of surgery unknown is checked. Please correct.' (Site from System).	System	01 Sep 2020 21:09:06
User closed query 'Post-menopausal has not been entered, however date of last menstruation is provided, or Date of last menstruation unknown is checked. Please correct.' (Site from System).	System	01 Sep 2020 21:09:06
User entered 'Post-menopausal (POST-MENOPAUSAL)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 21:09:06
User opened query 'Post-menopausal has not been entered, however date of last menstruation is provided, or Date of last menstruation unknown is checked. Please correct.' (Site from System).	System	01 Sep 2020 21:08:09
User closed query 'Surgically sterile has not been entered, however date of surgery is provided, or Date of surgery unknown is checked. Please correct.' (Site from System).	System	01 Sep 2020 21:08:09
User entered 'Surgically sterile (SURGICALLY STERILE)' reason for change: Per Query Resolution	(b) (4), (b) (6)	01 Sep 2020 21:08:09
User opened query 'Surgically sterile has not been entered, however date of surgery is provided, or Date of surgery unknown is checked. Please correct.' (Site from System).	System	01 Sep 2020 21:07:40
User closed query 'Post-menopausal has not been entered, however date of last menstruation is provided, or Date of last menstruation unknown is checked. Please correct.' (Site from System).	System	01 Sep 2020 21:07:40
User entered 'Post-menopausal (POST-MENOPAUSAL)' reason for change: Per Query Resolution	(b) (4), (b) (6)	01 Sep 2020 21:07:40
User opened query 'Post-menopausal has not been entered, however date of last menstruation is provided, or Date of last menstruation unknown is checked. Please correct.' (Site from System).	System	01 Sep 2020 16:48:14

US3752153

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:15:20

[If No, what is the reason?](#)

Audit	User	Time (GMT)
User closed query 'Surgically sterile has not been entered, however date of surgery is provided, or Date of surgery unknown is checked. Please correct.' (Site from System).	System	01 Sep 2020 16:48:14
User entered 'Surgically sterile (SURGICALLY STERILE)' reason for change: Data Entry Error	Lauren Evans (b) (4)	01 Sep 2020 16:48:14
User opened query 'Surgically sterile has not been entered, however date of surgery is provided, or Date of surgery unknown is checked. Please correct.' (Site from System).	System	19 Aug 2020 21:15:59
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4), (b) (6)	19 Aug 2020 21:15:59

US3752153

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 21:15:59

US3752153

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User closed query 'Surgically sterile been entered, however date of surgery is missing. Please provide.' (Site from System).	System	05 Oct 2020 15:07:11
User entered 'un UNK 1994' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 15:07:11
User opened query 'Surgically sterile been entered, however date of surgery is missing. Please provide.' (Site from System).	System	05 Oct 2020 15:06:08
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 21:14:40
User entered 'un UNK 1994'	(b) (4), (b) (6)	19 Aug 2020 21:15:59

US3752153

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:15:20

[Date of surgery unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 21:15:59

US3752153

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	05 Oct 2020 15:09:22
User closed query 'Date of last menstruation is provided, however, date of last menstruation unknown is checked. Please correct.' (Site from System).	System	01 Sep 2020 21:14:14
User opened query 'Date of last menstruation is provided, however, date of last menstruation unknown is checked. Please correct.' (Site from System).	System	01 Sep 2020 21:14:00
User closed query 'Date of last menstruation is provided, however, date of last menstruation unknown is checked. Please correct.' (Site from System).	System	01 Sep 2020 21:14:00
User entered '01 Jan 1994' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 21:14:00
User opened query 'Date of last menstruation is provided, however, date of last menstruation unknown is checked. Please correct.' (Site from System).	System	01 Sep 2020 21:07:52
User closed query 'Date of last menstruation is provided, however, date of last menstruation unknown is checked. Please correct.' (Site from System).	System	01 Sep 2020 16:48:47
User opened query 'Date of last menstruation is provided, however, date of last menstruation unknown is checked. Please correct.' (Site from System).	System	01 Sep 2020 16:48:39
User entered 'UN UNK 1994' reason for change: Data Entry Error	Lauren Evans (b) (4)	01 Sep 2020 16:48:39
User closed query 'Post-menopausal has been entered, however date of last menstruation is missing. Please provide.' (Site from System).	System	19 Aug 2020 21:16:43
User opened query 'Post-menopausal has been entered, however date of last menstruation is missing. Please provide.' (Site from System).	System	19 Aug 2020 21:15:59
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 21:15:59

US3752153

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:15:20

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0' reason for change: Per Query Resolution	(b) (4), (b) (6)	01 Sep 2020 21:14:14
User entered '1' reason for change: Per Query Resolution	(b) (4), (b) (6)	01 Sep 2020 21:07:52
User entered '0' reason for change: Data Entry Error	Lauren Evans (b) (4)	01 Sep 2020 16:48:47
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 21:16:43
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 21:15:59

US3752153

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 21:18:30

US3752153

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 21:18:30

US3752153

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:20

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)'	(b) (4), (b) (6)	19 Aug 2020 21:18:30

US3752153

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 21:18:30

US3752153

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 21:18:30

US3752153

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 21:18:30

US3752153

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:20

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)'	(b) (4), (b) (6)	19 Aug 2020 21:18:30

US3752153

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:20

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)'	(b) (4), (b) (6)	19 Aug 2020 21:18:30

US3752153

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 21:18:30

US3752153

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:20

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)'	(b) (4), (b) (6)	19 Aug 2020 21:18:30

US3752153

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:20

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)'	(b) (4), (b) (6)	19 Aug 2020 21:18:30

US3752153

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:20

Other

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 21:18:30

US3752153

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:20

[Specify](#)

Audit	User	Time (GMT)
User entered 'Retired'	(b) (4), (b) (6)	19 Aug 2020 21:18:30

US3752153

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:20

No Risk Identified

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	19 Aug 2020 21:18:30

US3752153

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:20

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 21:18:30

US3752153

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:20

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'	(b) (4), (b) (6)	19 Aug 2020 21:18:30

US3752153

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 21:18:30

US3752153

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:20

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'	(b) (4), (b) (6)	19 Aug 2020 21:18:30

US3752153

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 21:18:30

US3752153

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:20

Other

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 21:18:30

US3752153

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:15:20

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 21:18:30

US3752153

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:15:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 21:18:56

US3752153

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered '19 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 21:18:56

US3752153

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	19 Aug 2020 21:18:56

US3752153

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:15:20

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	19 Aug 2020 21:18:56

US3752153

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:20

What was the date of randomization? (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '19 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	19 Aug 2020 17:09:39

US3752153

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:20

What was the participant's randomization number?

Audit	User	Time (GMT)
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 05:35:23
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:35:23
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Aug 2020 17:09:39
User entered '187017' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	19 Aug 2020 17:09:39

US3752153

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:20

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) 	19 Aug 2020 17:09:39

US3752153

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:20

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)'	(b) (4), (b) (6)	19 Aug 2020 21:19:10

US3752153

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:20

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 21:19:10

US3752153

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:20

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 21:19:10

US3752153

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:20

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 21:19:10

US3752153

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:20

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 21:19:10

US3752153

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:15:20

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 18:39:35
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:35:52
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:32:16

US3752153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:15:20

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 19:23:24
Query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly.'	(b) (4), (b) (6)	15 Sep 2020 14:08:01
answered with 'updated' (Site from DM).		
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 14:07:55
User opened query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 06:32:12
User entered '63.0' in	(b) (4), (b) (6)	19 Aug 2020 21:20:26

US3752153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:15:20

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 14:07:55
User entered '220.2' lb	(b) (4), (b) (6)	19 Aug 2020 21:20:26

US3752153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:15:20

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 19:23:24
Query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly.'	(b) (4), (b) (6)	15 Sep 2020 14:08:01
answered with 'updated' (Site from DM).		
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 14:07:55
User opened query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 06:32:12
User entered '63.0' in	(b) (4), (b) (6)	19 Aug 2020 21:20:26

US3752153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:15:20

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 14:07:55
User entered '220.2' lb	(b) (4), (b) (6)	19 Aug 2020 21:20:26

US3752153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:20

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	19 Aug 2020 21:20:26

US3752153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 21:20:26

US3752153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '19 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 21:20:26

US3752153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered '11:25'	(b) (4), (b) (6)	19 Aug 2020 21:20:26

US3752153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:25'	System	19 Aug 2020 21:20:26

US3752153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:20

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '098.1' F	(b) (4), (b) (6)	19 Aug 2020 21:20:26

US3752153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:20

[Route of measurement](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 21:20:55
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 21:20:55
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 21:20:26
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 21:20:26

US3752153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:20

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 21:20:26

US3752153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 21:20:55
Query 'Data is required. Please provide.' answered by System data change (Site from System).		19 Aug 2020 21:20:55
User entered '069' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 21:20:55
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 21:20:26
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 21:20:26

US3752153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:20

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	19 Aug 2020 21:20:55
User entered empty.	System	19 Aug 2020 21:20:26

US3752153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 21:20:55
Query 'Data is required. Please provide.' answered by System data change (Site from System).		19 Aug 2020 21:20:55
User entered '14' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 21:20:55
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 21:20:26
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 21:20:26

US3752153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	19 Aug 2020 21:20:55
User entered empty.	System	19 Aug 2020 21:20:26

US3752153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 21:20:55
Query 'Data is required. Please provide.' answered by System data change (Site from System).		19 Aug 2020 21:20:55
User entered '130' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 21:20:55
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 21:20:26
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 21:20:26

US3752153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Aug 2020 21:20:55
User entered empty.	System	19 Aug 2020 21:20:26

US3752153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 21:20:55
Query 'Data is required. Please provide.' answered by System data change (Site from System).		19 Aug 2020 21:20:55
User entered '080' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 21:20:55
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 21:20:26
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 21:20:26

US3752153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:20

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Aug 2020 21:20:55
User entered empty.	System	19 Aug 2020 21:20:26

US3752153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:15:20

Height

Audit	User	Time (GMT)
User closed query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 19:23:24
Query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly.'	(b) (4), (b) (6)	15 Sep 2020 14:08:01
answered with 'updated' (Site from DM).		
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 14:07:55
User opened query 'Per CDM: To avoid duplication of data the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day; HT and WT should only captured at screening and recorded as ND at Day 1. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 06:32:12
User entered '63.0' in	(b) (4), (b) (6)	19 Aug 2020 21:20:26

US3752153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:15:20

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 14:07:55
User entered '220.2' lb	(b) (4), (b) (6)	19 Aug 2020 21:20:26

US3752153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:20

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	19 Aug 2020 21:20:26

US3752153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 21:20:26

US3752153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '19 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 21:20:26

US3752153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:35:20
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		19 Aug 2020 21:20:26
User entered '13:15'	(b) (4), (b) (6)	19 Aug 2020 21:20:26

US3752153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered '19 Aug 2020 13:15'	System	19 Aug 2020 21:20:26

US3752153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:20

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 21:21:35
Query 'Data is required. Please provide.' answered by System data change (Site from System).		19 Aug 2020 21:21:35
User entered '98.1' F reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 21:21:35
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 21:20:26
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 21:20:26

US3752153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:20

[Route of measurement](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 21:21:35
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 21:21:35
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 21:20:26
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 21:20:26

US3752153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:20

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 21:20:26

US3752153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 21:21:35
Query 'Data is required. Please provide.' answered by System data change (Site from System).		19 Aug 2020 21:21:35
User entered '70' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 21:21:35
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 21:20:26
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 21:20:26

US3752153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:20

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	19 Aug 2020 21:21:35
User entered empty.	System	19 Aug 2020 21:20:26

US3752153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 21:21:35
Query 'Data is required. Please provide.' answered by System data change (Site from System).		19 Aug 2020 21:21:35
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 21:21:35
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 21:20:26
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 21:20:26

US3752153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	19 Aug 2020 21:21:35
User entered empty.	System	19 Aug 2020 21:20:26

US3752153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 21:21:35
Query 'Data is required. Please provide.' answered by System data change (Site from System).		19 Aug 2020 21:21:35
User entered '130' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 21:21:35
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 21:20:26
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 21:20:26

US3752153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Aug 2020 21:21:35
User entered empty.	System	19 Aug 2020 21:20:26

US3752153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 21:21:35
Query 'Data is required. Please provide.' answered by System data change (Site from System).		19 Aug 2020 21:21:35
User entered '70' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 21:21:35
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 21:20:26
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 21:20:26

US3752153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:20

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Aug 2020 21:21:35
User entered empty.	System	19 Aug 2020 21:20:26

US3752153

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:20

Was the physical examination performed?

Audit	User	Time (GMT)
User closed query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the PE form is only required to be completed using the PE form located in the screening folder. Completion of the PE form within the Visit 1 Day 1 folder should be left blank except for the response to "Was the physical examination performed?" This should be "No". Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 16:22:05
Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the PE form is only required to be completed using the PE form located in the screening folder. Completion of the PE form within the Visit 1 Day 1 folder should be left blank except for the response to "Was the physical examination performed?" This should be "No". Please update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 13:47:26
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 13:47:20
User opened query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the PE form is only required to be completed using the PE form located in the screening folder. Completion of the PE form within the Visit 1 Day 1 folder should be left blank except for the response to "Was the physical examination performed?" This should be "No". Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 20:45:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 21:21:48

US3752153

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:20

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	03 Sep 2020 13:47:20
User entered '19 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 21:21:48

US3752153

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:20

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 17:54:51

US3752153

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:20

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 17:54:51

US3752153

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 17:54:51

US3752153

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:20

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	19 Aug 2020 17:54:51

US3752153

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:20

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '19 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 17:54:51

US3752153

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:20

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '12:44'	(b) (4), (b) (6)	19 Aug 2020 17:54:51

US3752153

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:20

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 12:44'	System	19 Aug 2020 17:54:51

US3752153

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:20

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	19 Aug 2020 17:54:51

US3752153

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:20

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	19 Aug 2020 17:54:51

US3752153

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:15:20

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	19 Aug 2020 17:54:51

US3752153

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 21:22:33

US3752153

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered '19 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 21:22:33

US3752153

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:20

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '11:56'	(b) (4), (b) (6)	19 Aug 2020 21:22:33

US3752153

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:20

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:56'	System	19 Aug 2020 21:22:33

US3752153

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered '19 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 21:24:12

US3752153

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:15:20

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	19 Aug 2020 21:24:12

US3752153

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:15:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 21:24:12

US3752153

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:15:20

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered '11:54'	(b) (4), (b) (6)	19 Aug 2020 21:24:12

US3752153

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:15:20

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:54'	System	19 Aug 2020 21:24:12

US3752153

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:15:20

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	19 Aug 2020 21:24:12

US3752153

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:15:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 21:24:12

US3752153

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:15:20

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 21:24:12

US3752153

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:15:20

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:24:12

US3752153

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:15:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 21:24:33

US3752153

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:15:20

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 21:24:33

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 17:54:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-19T13:07:58', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '56a7c722-193f-42a4-8113-555dca1e9751'	System	19 Aug 2020 18:08:53
User entered 'Yes (Y)'	System	19 Aug 2020 18:08:53

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-19T13:08:16', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '56a7c722-193f-42a4-8113-555dca1e9751'	System	19 Aug 2020 18:08:53
User entered '98.1'	System	19 Aug 2020 18:08:53

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-19T13:08:35', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '56a7c722-193f-42a4-8113-555dca1e9751'	System	19 Aug 2020 18:08:53
User entered 'No (N)'	System	19 Aug 2020 18:08:53

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-19T13:08:47', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '56a7c722-193f-42a4-8113-555dca1e9751'	System	19 Aug 2020 18:08:53
User entered '19 Aug 2020 13:08'	System	19 Aug 2020 18:08:53

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 13:04'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 15:34'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 17:54:51
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-19T20:45:38', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '141e769c-b7a2-4b55-9cb6-5cd58190885d'	System	20 Aug 2020 01:46:16
User entered 'Yes (Y)'	System	20 Aug 2020 01:46:16

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-19T20:45:49', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '141e769c-b7a2-4b55-9cb6-5cd58190885d'	System	20 Aug 2020 01:46:16
User entered '96.6'	System	20 Aug 2020 01:46:16

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-19T20:45:53', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '141e769c-b7a2-4b55-9cb6-5cd58190885d'	System	20 Aug 2020 01:46:16
User entered 'No (N)'	System	20 Aug 2020 01:46:16

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-19T20:46:13', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '141e769c-b7a2-4b55-9cb6-5cd58190885d'	System	20 Aug 2020 01:46:16
User entered '19 Aug 2020 20:46'	System	20 Aug 2020 01:46:16

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 16:29'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 17:54:51
User entered 'Day 2'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-20T19:52:05', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'a06fe1fa-4ca8-4eb2-bdd3-360a4e5592fd'	System	21 Aug 2020 00:52:31
User entered 'Yes (Y)'	System	21 Aug 2020 00:52:31

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-20T19:52:15', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'a06fe1fa-4ca8-4eb2-bdd3-360a4e5592fd'	System	21 Aug 2020 00:52:31
User entered '95.9'	System	21 Aug 2020 00:52:31

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-20T19:52:21', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'a06fe1fa-4ca8-4eb2-bdd3-360a4e5592fd'	System	21 Aug 2020 00:52:31
User entered 'No (N)'	System	21 Aug 2020 00:52:31

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-20T19:52:29', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'a06fe1fa-4ca8-4eb2-bdd3-360a4e5592fd'	System	21 Aug 2020 00:52:31
User entered '20 Aug 2020 19:52'	System	21 Aug 2020 00:52:31

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 17:54:51
User entered 'Day 3'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-21T18:47:01', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '90430e12-adf1-47cc-af69-73e344415e19'	System	21 Aug 2020 23:47:32
User entered 'Yes (Y)'	System	21 Aug 2020 23:47:32

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-21T18:47:12', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '90430e12-adf1-47cc-af69-73e344415e19'	System	21 Aug 2020 23:47:32
User entered '95.5'	System	21 Aug 2020 23:47:32

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-21T18:47:16', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '90430e12-adf1-47cc-af69-73e344415e19'	System	21 Aug 2020 23:47:32
User entered 'No (N)'	System	21 Aug 2020 23:47:32

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-21T18:47:29', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '90430e12-adf1-47cc-af69-73e344415e19'	System	21 Aug 2020 23:47:32
User entered '21 Aug 2020 18:47'	System	21 Aug 2020 23:47:32

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 17:54:51
User entered 'Day 4'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:15:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-22T18:52:57', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '6b02a671-33f0-440b-ba6a-c9dc0087928b' User entered 'Yes (Y)'	System	22 Aug 2020 23:53:45
	System	22 Aug 2020 23:53:45

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:15:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-22T18:53:06', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '6b02a671-33f0-440b-ba6a-c9dc0087928b' User entered '95.6'	System	22 Aug 2020 23:53:45

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-22T18:53:11', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '6b02a671-33f0-440b-ba6a-c9dc0087928b'	System	22 Aug 2020 23:53:45
User entered 'No (N)'	System	22 Aug 2020 23:53:45

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:15:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-22T18:53:18', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '6b02a671-33f0-440b-ba6a-c9dc0087928b' User entered '22 Aug 2020 18:53'	System	22 Aug 2020 23:53:45
	System	22 Aug 2020 23:53:45

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 17:54:51
User entered 'Day 5'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:15:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-23T19:05:23', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '142b0fca-f838-4b64-8b2a-cc5fdcbad995'	System	24 Aug 2020 00:05:41
User entered 'Yes (Y)'	System	24 Aug 2020 00:05:41

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:15:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-23T19:05:30', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '142b0fca-f838-4b64-8b2a-cc5fdcbad995'	System	24 Aug 2020 00:05:41
User entered '97.1'	System	24 Aug 2020 00:05:41

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-23T19:05:34', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '142b0fca-f838-4b64-8b2a-cc5fdcbad995'	System	24 Aug 2020 00:05:41
User entered 'No (N)'	System	24 Aug 2020 00:05:41

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:15:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-23T19:05:39', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '142b0fca-f838-4b64-8b2a-cc5fdcbad995'	System	24 Aug 2020 00:05:41
User entered '23 Aug 2020 19:05'	System	24 Aug 2020 00:05:41

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 17:54:51
User entered 'Day 6'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:15:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-24T20:18:27', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'a56c0d8f-81f7-46df-8591-137036c4fd65'	System	25 Aug 2020 01:18:55
User entered 'Yes (Y)'	System	25 Aug 2020 01:18:55

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:15:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-24T20:18:37', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'a56c0d8f-81f7-46df-8591-137036c4fd65'	System	25 Aug 2020 01:18:55
User entered '94.8'	System	25 Aug 2020 01:18:55

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-24T20:18:42', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'a56c0d8f-81f7-46df-8591-137036c4fd65'	System	25 Aug 2020 01:18:55
User entered 'No (N)'	System	25 Aug 2020 01:18:55

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:15:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-24T20:18:49', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'a56c0d8f-81f7-46df-8591-137036c4fd65'	System	25 Aug 2020 01:18:55
User entered '24 Aug 2020 20:18'	System	25 Aug 2020 01:18:55

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 17:54:51
User entered 'Day 7'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:15:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-25T19:30:38', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '772ae827-6a07-4423-9187-c5c368356d53'	System	26 Aug 2020 00:31:08
User entered 'Yes (Y)'	System	26 Aug 2020 00:31:08

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:15:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-25T19:30:46', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '772ae827-6a07-4423-9187-c5c368356d53'	System	26 Aug 2020 00:31:08
User entered '96.7'	System	26 Aug 2020 00:31:08

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-25T19:30:54', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '772ae827-6a07-4423-9187-c5c368356d53'	System	26 Aug 2020 00:31:08
User entered 'No (N)'	System	26 Aug 2020 00:31:08

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:15:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-25T19:31:07', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '772ae827-6a07-4423-9187-c5c368356d53'	System	26 Aug 2020 00:31:08
User entered '25 Aug 2020 19:31'	System	26 Aug 2020 00:31:08

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 17:54:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

[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 (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-19T13:09:13', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '4efb1161-3a7c-4424-940c-5208320e31a4'	System	19 Aug 2020 18:10:18
User entered 'None (1)'	System	19 Aug 2020 18:10:18

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-19T13:09:46', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '4efb1161-3a7c-4424-940c-5208320e31a4'	System	19 Aug 2020 18:10:18
User entered 'No (N)'	System	19 Aug 2020 18:10:18

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-19T13:09:51', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '4efb1161-3a7c-4424-940c-5208320e31a4'	System	19 Aug 2020 18:10:18
User entered 'No (N)'	System	19 Aug 2020 18:10:18

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

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 (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-19T13:10:07', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '4efb1161-3a7c-4424-940c-5208320e31a4'	System	19 Aug 2020 18:10:18
User entered 'None (1)'	System	19 Aug 2020 18:10:18

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-19T13:10:16', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '4efb1161-3a7c-4424-940c-5208320e31a4'	System	19 Aug 2020 18:10:18
User entered '19 Aug 2020 13:10'	System	19 Aug 2020 18:10:18

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 13:04'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 15:34'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 17:54:51
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

[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 (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-19T20:46:38', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '00abcc3f-955e-4e66-acac-e910312ea618'	System	20 Aug 2020 01:47:25
User entered 'None (1)'	System	20 Aug 2020 01:47:25

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-19T20:46:42', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '00abcc3f-955e-4e66-acac-e910312ea618'	System	20 Aug 2020 01:47:25
User entered 'No (N)'	System	20 Aug 2020 01:47:25

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-19T20:46:47', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '00abcc3f-955e-4e66-acac-e910312ea618'	System	20 Aug 2020 01:47:25
User entered 'No (N)'	System	20 Aug 2020 01:47:25

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

[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 (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-19T20:46:56', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '00abcc3f-955e-4e66-acac-e910312ea618'	System	20 Aug 2020 01:47:25
User entered 'None (1)'	System	20 Aug 2020 01:47:25

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-19T20:47:21', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '00abcc3f-955e-4e66-acac-e910312ea618'	System	20 Aug 2020 01:47:25
User entered '19 Aug 2020 20:47'	System	20 Aug 2020 01:47:25

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 16:29'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 17:54:51
User entered 'Day 2'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:20

[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 (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-20T19:52:55', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '8c13bc5a-f261-498b-a0df-716ba3aa3a09'	System	21 Aug 2020 00:53:28
User entered 'Does not interfere with activity (2)'	System	21 Aug 2020 00:53:28

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-20T19:52:59', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '8c13bc5a-f261-498b-a0df-716ba3aa3a09'	System	21 Aug 2020 00:53:28
User entered 'No (N)'	System	21 Aug 2020 00:53:28

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-20T19:53:03', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '8c13bc5a-f261-498b-a0df-716ba3aa3a09'	System	21 Aug 2020 00:53:28
User entered 'No (N)'	System	21 Aug 2020 00:53:28

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:20

[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 (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-20T19:53:13', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '8c13bc5a-f261-498b-a0df-716ba3aa3a09'	System	21 Aug 2020 00:53:28
User entered 'None (1)'	System	21 Aug 2020 00:53:28

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-20T19:53:25', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '8c13bc5a-f261-498b-a0df-716ba3aa3a09'	System	21 Aug 2020 00:53:28
User entered '20 Aug 2020 19:53'	System	21 Aug 2020 00:53:28

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 17:54:51
User entered 'Day 3'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:20

[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 (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-21T18:47:38', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'e815d575-4105-47c4-a3e6-068b87fbfd29'	System	21 Aug 2020 23:48:01
User entered 'None (1)'	System	21 Aug 2020 23:48:01

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-21T18:47:42', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'e815d575-4105-47c4-a3e6-068b87fbfd29'	System	21 Aug 2020 23:48:01
User entered 'No (N)'	System	21 Aug 2020 23:48:01

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-21T18:47:46', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'e815d575-4105-47c4-a3e6-068b87fbfd29'	System	21 Aug 2020 23:48:01
User entered 'No (N)'	System	21 Aug 2020 23:48:01

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:20

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 (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-21T18:47:49', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'e815d575-4105-47c4-a3e6-068b87fbfd29'	System	21 Aug 2020 23:48:01
User entered 'None (1)'	System	21 Aug 2020 23:48:01

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-21T18:47:56', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'e815d575-4105-47c4-a3e6-068b87fbfd29'	System	21 Aug 2020 23:48:01
User entered '21 Aug 2020 18:47'	System	21 Aug 2020 23:48:01

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 17:54:51
User entered 'Day 4'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:20

[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 (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-22T18:53:26', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'd5ae75e9-c834-41ff-a810-66b5b32c9370'	System	22 Aug 2020 23:53:48
User entered 'None (1)'	System	22 Aug 2020 23:53:48

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-22T18:53:30', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'd5ae75e9-c834-41ff-a810-66b5b32c9370'	System	22 Aug 2020 23:53:48
User entered 'No (N)'	System	22 Aug 2020 23:53:48

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-22T18:53:33', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'd5ae75e9-c834-41ff-a810-66b5b32c9370'	System	22 Aug 2020 23:53:48
User entered 'No (N)'	System	22 Aug 2020 23:53:48

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:20

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 (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-22T18:53:38', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'd5ae75e9-c834-41ff-a810-66b5b32c9370'	System	22 Aug 2020 23:53:48
User entered 'None (1)'	System	22 Aug 2020 23:53:48

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-22T18:53:44', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'd5ae75e9-c834-41ff-a810-66b5b32c9370'	System	22 Aug 2020 23:53:48
User entered '22 Aug 2020 18:53'	System	22 Aug 2020 23:53:48

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 17:54:51
User entered 'Day 5'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:20

[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 (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-23T19:05:49', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '4ffe969c-b015-45f8-b82c-cd5abd549169'	System	24 Aug 2020 00:06:07
User entered 'None (1)'	System	24 Aug 2020 00:06:07

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-23T19:05:53', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '4ffe969c-b015-45f8-b82c-cd5abd549169'	System	24 Aug 2020 00:06:07
User entered 'No (N)'	System	24 Aug 2020 00:06:07

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-23T19:05:56', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '4ffe969c-b015-45f8-b82c-cd5abd549169'	System	24 Aug 2020 00:06:07
User entered 'No (N)'	System	24 Aug 2020 00:06:07

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:20

[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 (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-23T19:06:00', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '4ffe969c-b015-45f8-b82c-cd5abd549169'	System	24 Aug 2020 00:06:07
User entered 'None (1)'	System	24 Aug 2020 00:06:07

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-23T19:06:05', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '4ffe969c-b015-45f8-b82c-cd5abd549169'	System	24 Aug 2020 00:06:07
User entered '23 Aug 2020 19:06'	System	24 Aug 2020 00:06:07

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 17:54:51
User entered 'Day 6'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:20

[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 (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-24T20:18:58', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '9ef38983-a8e6-4204-855f-5fddc1100b8a'	System	25 Aug 2020 01:19:34
User entered 'None (1)'	System	25 Aug 2020 01:19:34

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-24T20:19:04', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '9ef38983-a8e6-4204-855f-5fddc1100b8a'	System	25 Aug 2020 01:19:34
User entered 'No (N)'	System	25 Aug 2020 01:19:34

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-24T20:19:14', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '9ef38983-a8e6-4204-855f-5fddc1100b8a'	System	25 Aug 2020 01:19:34
User entered 'No (N)'	System	25 Aug 2020 01:19:34

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:20

[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 (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-24T20:19:18', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '9ef38983-a8e6-4204-855f-5fddc1100b8a'	System	25 Aug 2020 01:19:34
User entered 'None (1)'	System	25 Aug 2020 01:19:34

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-24T20:19:30', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '9ef38983-a8e6-4204-855f-5fddc1100b8a'	System	25 Aug 2020 01:19:34
User entered '24 Aug 2020 20:19'	System	25 Aug 2020 01:19:34

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 17:54:51
User entered 'Day 7'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:20

[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 (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-25T19:31:13', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '98637150-f2ce-4747-b6b3-5d34f1df627d'	System	26 Aug 2020 00:31:32
User entered 'None (1)'	System	26 Aug 2020 00:31:32

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-25T19:31:17', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '98637150-f2ce-4747-b6b3-5d34f1df627d'	System	26 Aug 2020 00:31:32
User entered 'No (N)'	System	26 Aug 2020 00:31:32

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-25T19:31:19', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '98637150-f2ce-4747-b6b3-5d34f1df627d'	System	26 Aug 2020 00:31:32
User entered 'No (N)'	System	26 Aug 2020 00:31:32

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:20

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 (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-25T19:31:23', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '98637150-f2ce-4747-b6b3-5d34f1df627d'	System	26 Aug 2020 00:31:32
User entered 'None (1)'	System	26 Aug 2020 00:31:32

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-25T19:31:28', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '98637150-f2ce-4747-b6b3-5d34f1df627d'	System	26 Aug 2020 00:31:32
User entered '25 Aug 2020 19:31'	System	26 Aug 2020 00:31:32

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 17:54:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-19T13:10:27', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '53561e60-a91e-4d64-976a-a6efac9566c2'	System	19 Aug 2020 18:10:56
User entered 'None (0)'	System	19 Aug 2020 18:10:56

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-19T13:10:30', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '53561e60-a91e-4d64-976a-a6efac9566c2'	System	19 Aug 2020 18:10:56
User entered 'None (0)'	System	19 Aug 2020 18:10:56

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-19T13:10:32', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '53561e60-a91e-4d64-976a-a6efac9566c2'	System	19 Aug 2020 18:10:56
User entered 'None (0)'	System	19 Aug 2020 18:10:56

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-19T13:10:35', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '53561e60-a91e-4d64-976a-a6efac9566c2'	System	19 Aug 2020 18:10:56
User entered 'None (0)'	System	19 Aug 2020 18:10:56

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-19T13:10:37', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '53561e60-a91e-4d64-976a-a6efac9566c2'	System	19 Aug 2020 18:10:56
User entered 'None (0)'	System	19 Aug 2020 18:10:56

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-19T13:10:38', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '53561e60-a91e-4d64-976a-a6efac9566c2'	System	19 Aug 2020 18:10:56
User entered 'None (0)'	System	19 Aug 2020 18:10:56

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

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 (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-19T13:10:45', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '53561e60-a91e-4d64-976a-a6efac9566c2'	System	19 Aug 2020 18:10:56
User entered 'No (N)'	System	19 Aug 2020 18:10:56

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-19T13:10:53', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '53561e60-a91e-4d64-976a-a6efac9566c2'	System	19 Aug 2020 18:10:56
User entered '19 Aug 2020 13:10'	System	19 Aug 2020 18:10:56

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 13:04'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 15:34'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 17:54:51
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-19T20:47:30', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '0b5d0d5a-c879-4774-a8d6-6bc74eaa7240'	System	20 Aug 2020 01:48:24
User entered 'None (0)'	System	20 Aug 2020 01:48:24

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-19T20:47:37', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '0b5d0d5a-c879-4774-a8d6-6bc74eaa7240'	System	20 Aug 2020 01:48:24
User entered 'None (0)'	System	20 Aug 2020 01:48:24

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-19T20:47:41', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '0b5d0d5a-c879-4774-a8d6-6bc74eaa7240'	System	20 Aug 2020 01:48:24
User entered 'None (0)'	System	20 Aug 2020 01:48:24

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-19T20:47:50', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '0b5d0d5a-c879-4774-a8d6-6bc74eaa7240'	System	20 Aug 2020 01:48:24
User entered 'None (0)'	System	20 Aug 2020 01:48:24

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-19T20:47:54', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '0b5d0d5a-c879-4774-a8d6-6bc74eaa7240'	System	20 Aug 2020 01:48:24
User entered 'None (0)'	System	20 Aug 2020 01:48:24

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-19T20:47:59', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '0b5d0d5a-c879-4774-a8d6-6bc74eaa7240'	System	20 Aug 2020 01:48:24
User entered 'None (0)'	System	20 Aug 2020 01:48:24

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

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 (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-19T20:48:06', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '0b5d0d5a-c879-4774-a8d6-6bc74eaa7240'	System	20 Aug 2020 01:48:24
User entered 'No (N)'	System	20 Aug 2020 01:48:24

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-19T20:48:22', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '0b5d0d5a-c879-4774-a8d6-6bc74eaa7240'	System	20 Aug 2020 01:48:24
User entered '19 Aug 2020 20:48'	System	20 Aug 2020 01:48:24

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 16:29'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 17:54:51
User entered 'Day 2'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:20

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-20T19:53:31', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '85a4616b-10d0-48eb-b022-520ad5899917'	System	21 Aug 2020 00:54:37
User entered 'None (0)'	System	21 Aug 2020 00:54:37

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:20

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-20T19:53:42', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '85a4616b-10d0-48eb-b022-520ad5899917'	System	21 Aug 2020 00:54:37
User entered 'No interference with activity (1)'	System	21 Aug 2020 00:54:37

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-20T19:53:45', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '85a4616b-10d0-48eb-b022-520ad5899917'	System	21 Aug 2020 00:54:37
User entered 'None (0)'	System	21 Aug 2020 00:54:37

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-20T19:53:50', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '85a4616b-10d0-48eb-b022-520ad5899917'	System	21 Aug 2020 00:54:37
User entered 'None (0)'	System	21 Aug 2020 00:54:37

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-20T19:54:02', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '85a4616b-10d0-48eb-b022-520ad5899917'	System	21 Aug 2020 00:54:37
User entered 'None (0)'	System	21 Aug 2020 00:54:37

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:20

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-20T19:54:07', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '85a4616b-10d0-48eb-b022-520ad5899917'	System	21 Aug 2020 00:54:37
User entered 'None (0)'	System	21 Aug 2020 00:54:37

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:20

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 (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-20T19:54:14', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '85a4616b-10d0-48eb-b022-520ad5899917'	System	21 Aug 2020 00:54:37
User entered 'No (N)'	System	21 Aug 2020 00:54:37

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:20

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-20T19:54:35', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '85a4616b-10d0-48eb-b022-520ad5899917'	System	21 Aug 2020 00:54:37
User entered '20 Aug 2020 19:54'	System	21 Aug 2020 00:54:37

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 17:54:51
User entered 'Day 3'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:20

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-21T18:48:02', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'd8974acd-6c55-42da-8350-5152b41e0ced'	System	21 Aug 2020 23:48:36
User entered 'None (0)'	System	21 Aug 2020 23:48:36

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:20

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-21T18:48:06', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'd8974acd-6c55-42da-8350-5152b41e0ced' User entered 'None (0)'	System	21 Aug 2020 23:48:36
	System	21 Aug 2020 23:48:36

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-21T18:48:09', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'd8974acd-6c55-42da-8350-5152b41e0ced'	System	21 Aug 2020 23:48:36
User entered 'None (0)'	System	21 Aug 2020 23:48:36

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-21T18:48:13', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'd8974acd-6c55-42da-8350-5152b41e0ced' User entered 'None (0)'	System	21 Aug 2020 23:48:36
	System	21 Aug 2020 23:48:36

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-21T18:48:16', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'd8974acd-6c55-42da-8350-5152b41e0ced'	System	21 Aug 2020 23:48:36
User entered 'None (0)'	System	21 Aug 2020 23:48:36

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:20

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-21T18:48:19', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'd8974acd-6c55-42da-8350-5152b41e0ced' User entered 'None (0)'	System	21 Aug 2020 23:48:36
	System	21 Aug 2020 23:48:36

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:20

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 (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-21T18:48:23', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'd8974acd-6c55-42da-8350-5152b41e0ced'	System	21 Aug 2020 23:48:36
User entered 'No (N)'	System	21 Aug 2020 23:48:36

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:20

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-21T18:48:31', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'd8974acd-6c55-42da-8350-5152b41e0ced'	System	21 Aug 2020 23:48:36
User entered '21 Aug 2020 18:48'	System	21 Aug 2020 23:48:36

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 17:54:51
User entered 'Day 4'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:20

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-22T18:53:49', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '6d101232-6493-4c0c-9318-d15f3ebec1b2'	System	22 Aug 2020 23:54:21
User entered 'None (0)'	System	22 Aug 2020 23:54:21

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:20

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-22T18:53:52', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '6d101232-6493-4c0c-9318-d15f3ebec1b2'	System	22 Aug 2020 23:54:21
User entered 'None (0)'	System	22 Aug 2020 23:54:21

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-22T18:53:55', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '6d101232-6493-4c0c-9318-d15f3ebec1b2'	System	22 Aug 2020 23:54:21
User entered 'None (0)'	System	22 Aug 2020 23:54:21

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-22T18:53:58', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '6d101232-6493-4c0c-9318-d15f3ebec1b2'	System	22 Aug 2020 23:54:21
User entered 'None (0)'	System	22 Aug 2020 23:54:21

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-22T18:54:01', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '6d101232-6493-4c0c-9318-d15f3ebec1b2'	System	22 Aug 2020 23:54:21
User entered 'None (0)'	System	22 Aug 2020 23:54:21

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:20

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-22T18:54:04', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '6d101232-6493-4c0c-9318-d15f3ebec1b2'	System	22 Aug 2020 23:54:21
User entered 'None (0)'	System	22 Aug 2020 23:54:21

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:20

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 (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-22T18:54:08', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '6d101232-6493-4c0c-9318-d15f3ebec1b2'	System	22 Aug 2020 23:54:21
User entered 'No (N)'	System	22 Aug 2020 23:54:21

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:20

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-22T18:54:17', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '6d101232-6493-4c0c-9318-d15f3ebec1b2'	System	22 Aug 2020 23:54:21
User entered '22 Aug 2020 18:54'	System	22 Aug 2020 23:54:21

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 17:54:51
User entered 'Day 5'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:20

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-23T19:06:10', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '1aa7799f-2647-4562-a658-c6cd38eab0c3'	System	24 Aug 2020 00:06:37
User entered 'None (0)'	System	24 Aug 2020 00:06:37

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:20

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-23T19:06:13', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '1aa7799f-2647-4562-a658-c6cd38eab0c3'	System	24 Aug 2020 00:06:37
User entered 'None (0)'	System	24 Aug 2020 00:06:37

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-23T19:06:15', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '1aa7799f-2647-4562-a658-c6cd38eab0c3'	System	24 Aug 2020 00:06:37
User entered 'None (0)'	System	24 Aug 2020 00:06:37

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-23T19:06:19', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '1aa7799f-2647-4562-a658-c6cd38eab0c3'	System	24 Aug 2020 00:06:37
User entered 'None (0)'	System	24 Aug 2020 00:06:37

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-23T19:06:22', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '1aa7799f-2647-4562-a658-c6cd38eab0c3'	System	24 Aug 2020 00:06:37
User entered 'None (0)'	System	24 Aug 2020 00:06:37

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:20

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-23T19:06:24', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '1aa7799f-2647-4562-a658-c6cd38eab0c3'	System	24 Aug 2020 00:06:37
User entered 'None (0)'	System	24 Aug 2020 00:06:37

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:20

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 (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-23T19:06:28', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '1aa7799f-2647-4562-a658-c6cd38eab0c3'	System	24 Aug 2020 00:06:37
User entered 'No (N)'	System	24 Aug 2020 00:06:37

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:20

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-23T19:06:35', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '1aa7799f-2647-4562-a658-c6cd38eab0c3'	System	24 Aug 2020 00:06:37
User entered '23 Aug 2020 19:06'	System	24 Aug 2020 00:06:37

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 17:54:51
User entered 'Day 6'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:20

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-24T20:19:35', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '2d9799d1-5ebb-4c60-8512-2360407092e1'	System	25 Aug 2020 01:20:17
User entered 'None (0)'	System	25 Aug 2020 01:20:17

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:20

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-24T20:19:38', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '2d9799d1-5ebb-4c60-8512-2360407092e1'	System	25 Aug 2020 01:20:17
User entered 'None (0)'	System	25 Aug 2020 01:20:17

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-24T20:19:41', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '2d9799d1-5ebb-4c60-8512-2360407092e1'	System	25 Aug 2020 01:20:17
User entered 'None (0)'	System	25 Aug 2020 01:20:17

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-24T20:19:45', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '2d9799d1-5ebb-4c60-8512-2360407092e1'	System	25 Aug 2020 01:20:17
User entered 'None (0)'	System	25 Aug 2020 01:20:17

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-24T20:19:51', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '2d9799d1-5ebb-4c60-8512-2360407092e1'	System	25 Aug 2020 01:20:17
User entered 'None (0)'	System	25 Aug 2020 01:20:17

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:20

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-24T20:20:00', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '2d9799d1-5ebb-4c60-8512-2360407092e1'	System	25 Aug 2020 01:20:17
User entered 'None (0)'	System	25 Aug 2020 01:20:17

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:20

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 (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-24T20:20:06', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '2d9799d1-5ebb-4c60-8512-2360407092e1'	System	25 Aug 2020 01:20:17
User entered 'No (N)'	System	25 Aug 2020 01:20:17

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:20

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-24T20:20:15', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '2d9799d1-5ebb-4c60-8512-2360407092e1'	System	25 Aug 2020 01:20:17
User entered '24 Aug 2020 20:20'	System	25 Aug 2020 01:20:17

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 17:54:51
User entered 'Day 7'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:20

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-25T19:31:35', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '0963f5e2-b714-4d45-bf19-dec604f83fe4'	System	26 Aug 2020 00:32:18
User entered 'None (0)'	System	26 Aug 2020 00:32:18

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:20

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-25T19:31:41', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '0963f5e2-b714-4d45-bf19-dec604f83fe4'	System	26 Aug 2020 00:32:18
User entered 'None (0)'	System	26 Aug 2020 00:32:18

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-25T19:31:45', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '0963f5e2-b714-4d45-bf19-dec604f83fe4'	System	26 Aug 2020 00:32:18
User entered 'None (0)'	System	26 Aug 2020 00:32:18

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-25T19:31:48', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '0963f5e2-b714-4d45-bf19-dec604f83fe4'	System	26 Aug 2020 00:32:18
User entered 'None (0)'	System	26 Aug 2020 00:32:18

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-25T19:31:55', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '0963f5e2-b714-4d45-bf19-dec604f83fe4'	System	26 Aug 2020 00:32:18
User entered 'None (0)'	System	26 Aug 2020 00:32:18

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:20

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-25T19:31:59', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '0963f5e2-b714-4d45-bf19-dec604f83fe4'	System	26 Aug 2020 00:32:18
User entered 'None (0)'	System	26 Aug 2020 00:32:18

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:20

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 (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-25T19:32:05', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '0963f5e2-b714-4d45-bf19-dec604f83fe4'	System	26 Aug 2020 00:32:18
User entered 'No (N)'	System	26 Aug 2020 00:32:18

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:20

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-08-25T19:32:14', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '0963f5e2-b714-4d45-bf19-dec604f83fe4'	System	26 Aug 2020 00:32:18
User entered '25 Aug 2020 19:32'	System	26 Aug 2020 00:32:18

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 17:54:51

US3752153

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 17:54:51

US3752153

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	22 Oct 2020 19:57:11

US3752153

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered '26 Aug 2020'	Amanda Horn (b) (4) (b) (4)	22 Oct 2020 19:57:11

US3752153

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Amanda Horn (b) (4) (b) (4)	22 Oct 2020 19:57:11

US3752153

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Amanda Horn (b) (4) (b) (4)	22 Oct 2020 19:57:11

US3752153

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 14:39:13

US3752153

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:20

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 14:39:13

US3752153

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	22 Sep 2020 18:53:11

US3752153

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:20

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '2 Sep 2020'	Amanda Horn (b) (4) (b) (4)	22 Sep 2020 18:53:11

US3752153

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Amanda Horn (b) (4) (b) (4)	22 Sep 2020 18:53:11

US3752153

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Amanda Horn (b) (4) (b) (4)	22 Sep 2020 18:53:11

US3752153

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 14:39:22

US3752153

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:20

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 14:39:22

US3752153

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	22 Sep 2020 18:51:43

US3752153

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:20

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '9 Sep 2020'	Amanda Horn (b) (4) (b) (4)	22 Sep 2020 18:51:43

US3752153

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Amanda Horn (b) (4) (b) (4)	22 Sep 2020 18:51:43

US3752153

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Amanda Horn (b) (4) (b) (4)	22 Sep 2020 18:51:43

US3752153

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 14:39:32

US3752153

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:20

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 14:39:32

US3752153

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 14:40:01

US3752153

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered '16 Sep 2020'	(b) (4), (b) (6)	16 Sep 2020 14:40:01

US3752153

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	16 Sep 2020 14:40:01

US3752153

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:20

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	16 Sep 2020 14:40:01

US3752153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:20

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	16 Sep 2020 20:14:43

US3752153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 20:14:43

US3752153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered '16 Sep 2020'	(b) (4), (b) (6)	16 Sep 2020 20:14:43

US3752153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered '09:05'	(b) (4), (b) (6)	16 Sep 2020 20:14:43

US3752153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User entered '16 Sep 2020 09:05'	System	16 Sep 2020 20:14:43

US3752153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:20

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.1' F	(b) (4), (b) (6)	16 Sep 2020 20:14:43

US3752153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:20

[Route of measurement](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	16 Sep 2020 20:15:04
Query 'Data is required. Please provide.' answered by System data change (Site from System).		16 Sep 2020 20:15:04
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 20:15:04
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Sep 2020 20:14:43
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 20:14:43

US3752153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:20

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 20:14:43

US3752153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	16 Sep 2020 20:15:04
Query 'Data is required. Please provide.' answered by System data change (Site from System).		16 Sep 2020 20:15:04
User entered '68' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 20:15:04
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Sep 2020 20:14:43
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 20:14:43

US3752153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:20

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	16 Sep 2020 20:15:04
User entered empty.	System	16 Sep 2020 20:14:43

US3752153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	16 Sep 2020 20:15:04
Query 'Data is required. Please provide.' answered by System data change (Site from System).		16 Sep 2020 20:15:04
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6) [REDACTED]	16 Sep 2020 20:15:04
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Sep 2020 20:14:43
User entered empty.	(b) (4), (b) (6) [REDACTED]	16 Sep 2020 20:14:43

US3752153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	16 Sep 2020 20:15:04
User entered empty.	System	16 Sep 2020 20:14:43

US3752153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	16 Sep 2020 20:15:04
Query 'Data is required. Please provide.' answered by System data change (Site from System).		16 Sep 2020 20:15:04
User entered '130' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 20:15:04
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Sep 2020 20:14:43
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 20:14:43

US3752153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Sep 2020 20:15:04
User entered empty.	System	16 Sep 2020 20:14:43

US3752153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:20

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	16 Sep 2020 20:15:04
Query 'Data is required. Please provide.' answered by System data change (Site from System).		16 Sep 2020 20:15:04
User entered '78' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 20:15:04
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Sep 2020 20:14:43
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 20:14:43

US3752153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:15:20

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Sep 2020 20:15:04
User entered empty.	System	16 Sep 2020 20:14:43

US3752153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:20

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	16 Sep 2020 20:14:43

US3752153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 20:14:43

US3752153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Sep 2020'	(b) (4), (b) (6)	16 Sep 2020 20:14:43

US3752153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:20

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	16 Sep 2020 20:15:40
Query 'Data is required. Please provide.' answered by System data change (Site from System).		16 Sep 2020 20:15:40
User entered '09:55' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 20:15:40
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Sep 2020 20:14:43
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 20:14:43

US3752153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:20

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 09:55'	System	16 Sep 2020 20:15:40
User entered empty.	System	16 Sep 2020 20:14:43

US3752153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:20

Temperature (xxx.x)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	16 Sep 2020 20:15:40
Query 'Data is required. Please provide.' answered by System data change (Site from System).		16 Sep 2020 20:15:40
User entered '98.2' F reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 20:15:40
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Sep 2020 20:14:43
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 20:14:43

US3752153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:20

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 20:15:40
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 20:14:43

US3752153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:20

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 20:14:43

US3752153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	16 Sep 2020 20:15:40
Query 'Data is required. Please provide.' answered by System data change (Site from System).		16 Sep 2020 20:15:40
User entered '70' reason for change: Data Entry Error	(b) (4), (b) (6) [REDACTED]	16 Sep 2020 20:15:40
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Sep 2020 20:14:43
User entered empty.	(b) (4), (b) (6) [REDACTED]	16 Sep 2020 20:14:43

US3752153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:20

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	16 Sep 2020 20:15:40
User entered empty.	System	16 Sep 2020 20:14:43

US3752153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:20

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	16 Sep 2020 20:15:40
Query 'Data is required. Please provide.' answered by System data change (Site from System).		16 Sep 2020 20:15:40
User entered '18' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 20:15:40
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Sep 2020 20:14:43
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 20:14:43

US3752153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	16 Sep 2020 20:15:40
User entered empty.	System	16 Sep 2020 20:14:43

US3752153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:20

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	16 Sep 2020 20:15:40
Query 'Data is required. Please provide.' answered by System data change (Site from System).		16 Sep 2020 20:15:40
User entered '140' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 20:15:40
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Sep 2020 20:14:43
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 20:14:43

US3752153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Sep 2020 20:15:40
User entered empty.	System	16 Sep 2020 20:14:43

US3752153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:20

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	16 Sep 2020 20:15:40
Query 'Data is required. Please provide.' answered by System data change (Site from System).		16 Sep 2020 20:15:40
User entered '72' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 20:15:40
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Sep 2020 20:14:43
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 20:14:43

US3752153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:15:20

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	16 Sep 2020 20:15:40
User entered empty.	System	16 Sep 2020 20:14:43

US3752153

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 20:15:51

US3752153

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:20

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '16 Sep 2020'	(b) (4), (b) (6)	16 Sep 2020 20:15:51

US3752153

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:20

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 14:40:36

US3752153

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:20

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 14:40:36

US3752153

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:20

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 14:40:36

US3752153

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:20

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	16 Sep 2020 14:40:36

US3752153

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:20

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020'	(b) (4), (b) (6)	16 Sep 2020 14:40:36

US3752153

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:20

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '09:35'	(b) (4), (b) (6)	16 Sep 2020 14:40:36

US3752153

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:20

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 09:35'	System	16 Sep 2020 14:40:36

US3752153

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:20

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	16 Sep 2020 14:40:36

US3752153

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:20

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	16 Sep 2020 14:40:36

US3752153

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:15:20

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	16 Sep 2020 14:40:36

US3752153

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 20:16:10

US3752153

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:20

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020'	(b) (4), (b) (6)	16 Sep 2020 20:16:10

US3752153

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:20

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '09:22'	(b) (4), (b) (6)	16 Sep 2020 20:16:10

US3752153

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:20

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 09:22'	System	16 Sep 2020 20:16:10

US3752153

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:15:20

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	System	16 Sep 2020 20:16:36
Query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' answered by data change (Site from System).	System	16 Sep 2020 20:16:36
User entered '16 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Sep 2020 20:16:36
User opened query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	System	16 Sep 2020 20:16:26
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 20:16:26

US3752153

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:15:20

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	16 Sep 2020 20:16:26

US3752153

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:15:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 20:16:26

US3752153

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:15:20

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered '09:20'	(b) (4), (b) (6)	16 Sep 2020 20:16:26

US3752153

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:15:20

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 09:20'	System	16 Sep 2020 20:16:36
User entered empty.	System	16 Sep 2020 20:16:26

US3752153

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:15:20

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	16 Sep 2020 20:16:26

US3752153

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:15:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	16 Sep 2020 20:16:26

US3752153

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:15:20

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	16 Sep 2020 20:16:26

US3752153

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:15:20

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 20:16:26

US3752153

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Sep 2020 20:16:40

US3752153

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:20

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 20:16:40

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 14:40:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-16T10:00:54', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'ddb25d71-c2a7-4552-a30f-a95a4b695293'	System	16 Sep 2020 15:01:19
User entered 'Yes (Y)'	System	16 Sep 2020 15:01:19

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-16T10:01:04', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'ddb25d71-c2a7-4552-a30f-a95a4b695293'	System	16 Sep 2020 15:01:19
User entered '98.2'	System	16 Sep 2020 15:01:19

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-16T10:01:08', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'ddb25d71-c2a7-4552-a30f-a95a4b695293'	System	16 Sep 2020 15:01:19
User entered 'No (N)'	System	16 Sep 2020 15:01:19

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-16T10:01:16', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'ddb25d71-c2a7-4552-a30f-a95a4b695293'	System	16 Sep 2020 15:01:19
User entered '16 Sep 2020 10:01'	System	16 Sep 2020 15:01:19

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 09:55'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:25'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 14:40:36
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-16T20:24:24', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '3f6219a0-5653-4ff7-bb3f-663cd47d76e7'	System	17 Sep 2020 01:25:02
User entered 'Yes (Y)'	System	17 Sep 2020 01:25:02

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-16T20:24:34', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '3f6219a0-5653-4ff7-bb3f-663cd47d76e7'	System	17 Sep 2020 01:25:02
User entered '97.7'	System	17 Sep 2020 01:25:02

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-16T20:24:47', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '3f6219a0-5653-4ff7-bb3f-663cd47d76e7'	System	17 Sep 2020 01:25:02
User entered 'No (N)'	System	17 Sep 2020 01:25:02

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-16T20:24:59', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '3f6219a0-5653-4ff7-bb3f-663cd47d76e7'	System	17 Sep 2020 01:25:02
User entered '16 Sep 2020 20:24'	System	17 Sep 2020 01:25:02

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 13:20'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 14:40:36
User entered 'Day 2'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-17T16:17:26', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '3dd3b010-b1a3-4f57-90b1-869469e74353'	System	17 Sep 2020 21:17:51
User entered 'Yes (Y)'	System	17 Sep 2020 21:17:51

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-17T16:17:35', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '3dd3b010-b1a3-4f57-90b1-869469e74353'	System	17 Sep 2020 21:17:51
User entered '98.5'	System	17 Sep 2020 21:17:51

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:20

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-17T16:17:40', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '3dd3b010-b1a3-4f57-90b1-869469e74353'	System	17 Sep 2020 21:17:51
User entered 'No (N)'	System	17 Sep 2020 21:17:51

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-17T16:17:48', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '3dd3b010-b1a3-4f57-90b1-869469e74353'	System	17 Sep 2020 21:17:51
User entered '17 Sep 2020 16:17'	System	17 Sep 2020 21:17:51

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 14:40:36
User entered 'Day 3'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-18T19:41:21', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '4e3dfc51-378b-465b-9492-166dda456d05'	System	19 Sep 2020 00:41:44
User entered 'Yes (Y)'	System	19 Sep 2020 00:41:44

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-18T19:41:28', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '4e3dfc51-378b-465b-9492-166dda456d05'	System	19 Sep 2020 00:41:44
User entered '97.1'	System	19 Sep 2020 00:41:44

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:20

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-18T19:41:35', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '4e3dfc51-378b-465b-9492-166dda456d05'	System	19 Sep 2020 00:41:44
User entered 'No (N)'	System	19 Sep 2020 00:41:44

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-18T19:41:43', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '4e3dfc51-378b-465b-9492-166dda456d05'	System	19 Sep 2020 00:41:44
User entered '18 Sep 2020 19:41'	System	19 Sep 2020 00:41:44

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 14:40:36
User entered 'Day 4'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:15:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-19T20:59:32', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'a9397de3-ce19-4df6-b4e6-4489132757df'	System	20 Sep 2020 02:00:00
User entered 'Yes (Y)'	System	20 Sep 2020 02:00:00

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:15:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-19T20:59:39', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'a9397de3-ce19-4df6-b4e6-4489132757df'	System	20 Sep 2020 02:00:00
User entered '96.7'	System	20 Sep 2020 02:00:00

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:15:20

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-19T20:59:45', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'a9397de3-ce19-4df6-b4e6-4489132757df'	System	20 Sep 2020 02:00:00
User entered 'No (N)'	System	20 Sep 2020 02:00:00

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:15:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-19T20:59:56', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'a9397de3-ce19-4df6-b4e6-4489132757df'	System	20 Sep 2020 02:00:00
User entered '19 Sep 2020 20:59'	System	20 Sep 2020 02:00:00

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 14:40:36
User entered 'Day 5'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:15:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-20T20:30:06', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '4e216f48-4b3f-44bc-ae65-aeb1033dbd4f'	System	21 Sep 2020 01:30:27
User entered 'Yes (Y)'	System	21 Sep 2020 01:30:27

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:15:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-20T20:30:14', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '4e216f48-4b3f-44bc-ae65-aeb1033dbd4f'	System	21 Sep 2020 01:30:27
User entered '95.8'	System	21 Sep 2020 01:30:27

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:15:20

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-20T20:30:19', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '4e216f48-4b3f-44bc-ae65-aeb1033dbd4f'	System	21 Sep 2020 01:30:27
User entered 'No (N)'	System	21 Sep 2020 01:30:27

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:15:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-20T20:30:26', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '4e216f48-4b3f-44bc-ae65-aeb1033dbd4f'	System	21 Sep 2020 01:30:27
User entered '20 Sep 2020 20:30'	System	21 Sep 2020 01:30:27

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 14:40:36
User entered 'Day 6'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 14:40:36
User entered 'Day 7'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:15:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-22T20:48:46', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '754142f3-9516-4eb5-b5f4-0c0a0c88e5d7'	System	23 Sep 2020 01:49:14
User entered 'Yes (Y)'	System	23 Sep 2020 01:49:14

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:15:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-22T20:48:53', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '754142f3-9516-4eb5-b5f4-0c0a0c88e5d7'	System	23 Sep 2020 01:49:14
User entered '96.8'	System	23 Sep 2020 01:49:14

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:15:20

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-22T20:48:57', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '754142f3-9516-4eb5-b5f4-0c0a0c88e5d7'	System	23 Sep 2020 01:49:14
User entered 'No (N)'	System	23 Sep 2020 01:49:14

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:15:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-22T20:49:08', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '754142f3-9516-4eb5-b5f4-0c0a0c88e5d7'	System	23 Sep 2020 01:49:14
User entered '22 Sep 2020 20:49'	System	23 Sep 2020 01:49:14

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 14:40:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

[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 (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-16T10:01:28', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '0581b638-c182-4226-be03-f911f92f739b'	System	16 Sep 2020 15:01:48
User entered 'None (1)'	System	16 Sep 2020 15:01:48

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-16T10:01:32', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '0581b638-c182-4226-be03-f911f92f739b'	System	16 Sep 2020 15:01:48
User entered 'No (N)'	System	16 Sep 2020 15:01:48

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-16T10:01:35', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '0581b638-c182-4226-be03-f911f92f739b'	System	16 Sep 2020 15:01:48
User entered 'No (N)'	System	16 Sep 2020 15:01:48

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

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 (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-16T10:01:39', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '0581b638-c182-4226-be03-f911f92f739b'	System	16 Sep 2020 15:01:48
User entered 'None (1)'	System	16 Sep 2020 15:01:48

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-16T10:01:45', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '0581b638-c182-4226-be03-f911f92f739b'	System	16 Sep 2020 15:01:48
User entered '16 Sep 2020 10:01'	System	16 Sep 2020 15:01:48

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 09:55'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:25'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 14:40:36
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

[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 (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-16T20:25:22', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '92ef5412-c19a-4e8f-b15c-48a5e596a3fe'	System	17 Sep 2020 01:25:47
User entered 'None (1)'	System	17 Sep 2020 01:25:47

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-16T20:25:26', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '92ef5412-c19a-4e8f-b15c-48a5e596a3fe'	System	17 Sep 2020 01:25:47
User entered 'No (N)'	System	17 Sep 2020 01:25:47

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-16T20:25:30', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '92ef5412-c19a-4e8f-b15c-48a5e596a3fe'	System	17 Sep 2020 01:25:47
User entered 'No (N)'	System	17 Sep 2020 01:25:47

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

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 (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-16T20:25:35', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '92ef5412-c19a-4e8f-b15c-48a5e596a3fe'	System	17 Sep 2020 01:25:47
User entered 'None (1)'	System	17 Sep 2020 01:25:47

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-16T20:25:44', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '92ef5412-c19a-4e8f-b15c-48a5e596a3fe'	System	17 Sep 2020 01:25:47
User entered '16 Sep 2020 20:25'	System	17 Sep 2020 01:25:47

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 13:20'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 14:40:36
User entered 'Day 2'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:20

[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 (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-17T16:18:07', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '4636a818-4a83-447e-a1fe-b053a5d8e76a'	System	17 Sep 2020 21:21:14
User entered 'Does not interfere with activity (2)'	System	17 Sep 2020 21:21:14

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:20

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-17T16:18:12', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '4636a818-4a83-447e-a1fe-b053a5d8e76a'	System	17 Sep 2020 21:21:14
User entered 'Yes (Y)'	System	17 Sep 2020 21:21:14

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:20

Please record - REDNESS AT INJECTION SITE (in mm)

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-17T16:18:25', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '4636a818-4a83-447e-a1fe-b053a5d8e76a' User entered '6'	System	17 Sep 2020 21:21:14
	System	17 Sep 2020 21:21:14

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:20

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-17T16:20:17', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '4636a818-4a83-447e-a1fe-b053a5d8e76a'	System	17 Sep 2020 21:21:14
User entered 'Yes (Y)'	System	17 Sep 2020 21:21:14

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:20

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-17T16:20:36', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '4636a818-4a83-447e-a1fe-b053a5d8e76a' User entered '6'	System	17 Sep 2020 21:21:14
	System	17 Sep 2020 21:21:14

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:20

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 (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-17T16:20:51', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '4636a818-4a83-447e-a1fe-b053a5d8e76a'	System	17 Sep 2020 21:21:14
User entered 'None (1)'	System	17 Sep 2020 21:21:14

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-17T16:21:11', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '4636a818-4a83-447e-a1fe-b053a5d8e76a'	System	17 Sep 2020 21:21:14
User entered '17 Sep 2020 16:21'	System	17 Sep 2020 21:21:14

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 14:40:36
User entered 'Day 3'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:20

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 (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-18T19:41:59', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '77976ff0-1fe6-4603-b047-dd566d61d56b'	System	19 Sep 2020 00:43:36
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	19 Sep 2020 00:43:36

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:20

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-18T19:42:02', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '77976ff0-1fe6-4603-b047-dd566d61d56b'	System	19 Sep 2020 00:43:36
User entered 'Yes (Y)'	System	19 Sep 2020 00:43:36

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:20

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-18T19:42:18', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '77976ff0-1fe6-4603-b047-dd566d61d56b' User entered '8'	System	19 Sep 2020 00:43:36
	System	19 Sep 2020 00:43:36

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:20

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-18T19:42:23', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '77976ff0-1fe6-4603-b047-dd566d61d56b'	System	19 Sep 2020 00:43:36
User entered 'Yes (Y)'	System	19 Sep 2020 00:43:36

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:20

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-18T19:42:46', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '77976ff0-1fe6-4603-b047-dd566d61d56b' User entered '8'	System	19 Sep 2020 00:43:36
	System	19 Sep 2020 00:43:36

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:20

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 (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-18T19:42:52', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '77976ff0-1fe6-4603-b047-dd566d61d56b'	System	19 Sep 2020 00:43:36
User entered 'None (1)'	System	19 Sep 2020 00:43:36

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-18T19:43:31', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '77976ff0-1fe6-4603-b047-dd566d61d56b'	System	19 Sep 2020 00:43:36
User entered '18 Sep 2020 19:43'	System	19 Sep 2020 00:43:36

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 14:40:36
User entered 'Day 4'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:20

[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 (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-19T21:00:05', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '32286135-68f6-4b20-9dd2-d9fc71be4f5b'	System	20 Sep 2020 02:01:02
User entered 'Does not interfere with activity (2)'	System	20 Sep 2020 02:01:02

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-19T21:00:11', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '32286135-68f6-4b20-9dd2-d9fc71be4f5b'	System	20 Sep 2020 02:01:02
User entered 'Yes (Y)'	System	20 Sep 2020 02:01:02

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:20

Please record - REDNESS AT INJECTION SITE (in mm)

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-19T21:00:22', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '32286135-68f6-4b20-9dd2-d9fc71be4f5b' User entered '6'	System	20 Sep 2020 02:01:02
	System	20 Sep 2020 02:01:02

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:20

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-19T21:00:26', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '32286135-68f6-4b20-9dd2-d9fc71be4f5b'	System	20 Sep 2020 02:01:02
User entered 'Yes (Y)'	System	20 Sep 2020 02:01:02

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:20

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-19T21:00:36', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '32286135-68f6-4b20-9dd2-d9fc71be4f5b' User entered '6'	System	20 Sep 2020 02:01:02
	System	20 Sep 2020 02:01:02

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:20

[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 (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-19T21:00:41', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '32286135-68f6-4b20-9dd2-d9fc71be4f5b'	System	20 Sep 2020 02:01:02
User entered 'None (1)'	System	20 Sep 2020 02:01:02

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-19T21:00:58', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '32286135-68f6-4b20-9dd2-d9fc71be4f5b'	System	20 Sep 2020 02:01:02
User entered '19 Sep 2020 21:00'	System	20 Sep 2020 02:01:02

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 14:40:36
User entered 'Day 5'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:20

[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 (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-20T20:30:33', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '5ceb4ddc-53b6-4c00-82dd-9cc0b00e2c25'	System	21 Sep 2020 01:31:21
User entered 'Does not interfere with activity (2)'	System	21 Sep 2020 01:31:21

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:20

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-20T20:30:37', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '5ceb4ddc-53b6-4c00-82dd-9cc0b00e2c25'	System	21 Sep 2020 01:31:21
User entered 'Yes (Y)'	System	21 Sep 2020 01:31:21

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:20

[Please record - REDNESS AT INJECTION SITE \(in mm\)](#)

[Measure the largest size across any injection site redness with the ruler provided.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-20T20:30:43', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '5ceb4ddc-53b6-4c00-82dd-9cc0b00e2c25' User entered '6'	System	21 Sep 2020 01:31:21
	System	21 Sep 2020 01:31:21

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:20

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-20T20:30:49', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '5ceb4ddc-53b6-4c00-82dd-9cc0b00e2c25'	System	21 Sep 2020 01:31:21
User entered 'Yes (Y)'	System	21 Sep 2020 01:31:21

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:20

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-20T20:30:58', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '5ceb4ddc-53b6-4c00-82dd-9cc0b00e2c25' User entered '6'	System	21 Sep 2020 01:31:21
	System	21 Sep 2020 01:31:21

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:20

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 (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-20T20:31:03', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '5ceb4ddc-53b6-4c00-82dd-9cc0b00e2c25'	System	21 Sep 2020 01:31:21
User entered 'None (1)'	System	21 Sep 2020 01:31:21

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-20T20:31:19', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '5ceb4ddc-53b6-4c00-82dd-9cc0b00e2c25'	System	21 Sep 2020 01:31:21
User entered '20 Sep 2020 20:31'	System	21 Sep 2020 01:31:21

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 14:40:36
User entered 'Day 6'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 14:40:36
User entered 'Day 7'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:20

[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 (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-22T20:49:15', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '0efc64a5-8312-4926-94ec-319676809a75'	System	23 Sep 2020 01:50:17
User entered 'Does not interfere with activity (2)'	System	23 Sep 2020 01:50:17

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-22T20:49:20', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '0efc64a5-8312-4926-94ec-319676809a75'	System	23 Sep 2020 01:50:17
User entered 'Yes (Y)'	System	23 Sep 2020 01:50:17

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:20

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-22T20:49:27', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '0efc64a5-8312-4926-94ec-319676809a75' User entered '6'	System	23 Sep 2020 01:50:17
	System	23 Sep 2020 01:50:17

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:20

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-22T20:49:33', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '0efc64a5-8312-4926-94ec-319676809a75'	System	23 Sep 2020 01:50:17
User entered 'Yes (Y)'	System	23 Sep 2020 01:50:17

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:20

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-22T20:49:37', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '0efc64a5-8312-4926-94ec-319676809a75' User entered '6'	System	23 Sep 2020 01:50:17
	System	23 Sep 2020 01:50:17

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:20

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 (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-22T20:49:41', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '0efc64a5-8312-4926-94ec-319676809a75'	System	23 Sep 2020 01:50:17
User entered 'None (1)'	System	23 Sep 2020 01:50:17

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-22T20:49:52', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '0efc64a5-8312-4926-94ec-319676809a75'	System	23 Sep 2020 01:50:17
User entered '22 Sep 2020 20:49'	System	23 Sep 2020 01:50:17

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 14:40:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-16T10:01:56', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '9e1a55aa-a89c-4ebe-909f-1d06f7c53109'	System	16 Sep 2020 15:02:30
User entered 'None (0)'	System	16 Sep 2020 15:02:30

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-16T10:02:01', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '9e1a55aa-a89c-4ebe-909f-1d06f7c53109'	System	16 Sep 2020 15:02:30
User entered 'None (0)'	System	16 Sep 2020 15:02:30

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-16T10:02:04', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '9e1a55aa-a89c-4ebe-909f-1d06f7c53109'	System	16 Sep 2020 15:02:30
User entered 'None (0)'	System	16 Sep 2020 15:02:30

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-16T10:02:08', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '9e1a55aa-a89c-4ebe-909f-1d06f7c53109'	System	16 Sep 2020 15:02:30
User entered 'None (0)'	System	16 Sep 2020 15:02:30

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-16T10:02:11', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '9e1a55aa-a89c-4ebe-909f-1d06f7c53109'	System	16 Sep 2020 15:02:30
User entered 'None (0)'	System	16 Sep 2020 15:02:30

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-16T10:02:15', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '9e1a55aa-a89c-4ebe-909f-1d06f7c53109'	System	16 Sep 2020 15:02:30
User entered 'None (0)'	System	16 Sep 2020 15:02:30

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

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 (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-16T10:02:20', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '9e1a55aa-a89c-4ebe-909f-1d06f7c53109'	System	16 Sep 2020 15:02:30
User entered 'No (N)'	System	16 Sep 2020 15:02:30

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-16T10:02:28', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '9e1a55aa-a89c-4ebe-909f-1d06f7c53109'	System	16 Sep 2020 15:02:30
User entered '16 Sep 2020 10:02'	System	16 Sep 2020 15:02:30

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 09:55'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:25'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 14:40:36
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-16T20:25:56', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'fab17592-c7a9-47c5-9322-ff30dc27f504'	System	17 Sep 2020 01:26:40
User entered 'None (0)'	System	17 Sep 2020 01:26:40

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-16T20:26:00', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'fab17592-c7a9-47c5-9322-ff30dc27f504'	System	17 Sep 2020 01:26:40
User entered 'None (0)'	System	17 Sep 2020 01:26:40

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-16T20:26:06', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'fab17592-c7a9-47c5-9322-ff30dc27f504'	System	17 Sep 2020 01:26:40
User entered 'None (0)'	System	17 Sep 2020 01:26:40

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-16T20:26:11', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'fab17592-c7a9-47c5-9322-ff30dc27f504'	System	17 Sep 2020 01:26:40
User entered 'None (0)'	System	17 Sep 2020 01:26:40

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-16T20:26:15', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'fab17592-c7a9-47c5-9322-ff30dc27f504'	System	17 Sep 2020 01:26:40
User entered 'None (0)'	System	17 Sep 2020 01:26:40

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-16T20:26:20', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'fab17592-c7a9-47c5-9322-ff30dc27f504'	System	17 Sep 2020 01:26:40
User entered 'None (0)'	System	17 Sep 2020 01:26:40

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

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 (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-16T20:26:25', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'fab17592-c7a9-47c5-9322-ff30dc27f504'	System	17 Sep 2020 01:26:40
User entered 'No (N)'	System	17 Sep 2020 01:26:40

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-16T20:26:38', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'fab17592-c7a9-47c5-9322-ff30dc27f504'	System	17 Sep 2020 01:26:40
User entered '16 Sep 2020 20:26'	System	17 Sep 2020 01:26:40

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 13:20'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 14:40:36
User entered 'Day 2'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:20

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-17T16:21:21', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'f4a78f3c-81e5-409e-925e-336048996a51'	System	17 Sep 2020 21:22:29
User entered 'No interference with activity (1)'	System	17 Sep 2020 21:22:29

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:20

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-17T16:21:37', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'f4a78f3c-81e5-409e-925e-336048996a51'	System	17 Sep 2020 21:22:29
User entered 'No interference with activity (1)'	System	17 Sep 2020 21:22:29

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-17T16:21:44', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'f4a78f3c-81e5-409e-925e-336048996a51'	System	17 Sep 2020 21:22:29
User entered 'Some interference with activity (2)'	System	17 Sep 2020 21:22:29

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-17T16:21:50', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'f4a78f3c-81e5-409e-925e-336048996a51'	System	17 Sep 2020 21:22:29
User entered 'Some interference with activity (2)'	System	17 Sep 2020 21:22:29

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-17T16:21:54', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'f4a78f3c-81e5-409e-925e-336048996a51'	System	17 Sep 2020 21:22:29
User entered 'None (0)'	System	17 Sep 2020 21:22:29

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:20

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-17T16:21:58', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'f4a78f3c-81e5-409e-925e-336048996a51'	System	17 Sep 2020 21:22:29
User entered 'None (0)'	System	17 Sep 2020 21:22:29

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:20

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 (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-17T16:22:10', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'f4a78f3c-81e5-409e-925e-336048996a51'	System	17 Sep 2020 21:22:29
User entered 'No (N)'	System	17 Sep 2020 21:22:29

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:20

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-17T16:22:27', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'f4a78f3c-81e5-409e-925e-336048996a51'	System	17 Sep 2020 21:22:29
User entered '17 Sep 2020 16:22'	System	17 Sep 2020 21:22:29

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 14:40:36
User entered 'Day 3'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 14:40:36
User entered 'Day 4'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:20

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-19T21:01:04', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '9887ba4d-285e-4d35-859f-8c732a6fa1c4'	System	20 Sep 2020 02:01:47
User entered 'None (0)'	System	20 Sep 2020 02:01:47

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:20

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-19T21:01:17', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '9887ba4d-285e-4d35-859f-8c732a6fa1c4'	System	20 Sep 2020 02:01:47
User entered 'None (0)'	System	20 Sep 2020 02:01:47

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-19T21:01:21', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '9887ba4d-285e-4d35-859f-8c732a6fa1c4'	System	20 Sep 2020 02:01:47
User entered 'None (0)'	System	20 Sep 2020 02:01:47

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-19T21:01:24', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '9887ba4d-285e-4d35-859f-8c732a6fa1c4'	System	20 Sep 2020 02:01:47
User entered 'None (0)'	System	20 Sep 2020 02:01:47

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-19T21:01:28', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '9887ba4d-285e-4d35-859f-8c732a6fa1c4'	System	20 Sep 2020 02:01:47
User entered 'None (0)'	System	20 Sep 2020 02:01:47

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:20

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-19T21:01:31', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '9887ba4d-285e-4d35-859f-8c732a6fa1c4'	System	20 Sep 2020 02:01:47
User entered 'None (0)'	System	20 Sep 2020 02:01:47

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:20

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 (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-19T21:01:37', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '9887ba4d-285e-4d35-859f-8c732a6fa1c4'	System	20 Sep 2020 02:01:47
User entered 'No (N)'	System	20 Sep 2020 02:01:47

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:20

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-19T21:01:45', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '9887ba4d-285e-4d35-859f-8c732a6fa1c4'	System	20 Sep 2020 02:01:47
User entered '19 Sep 2020 21:01'	System	20 Sep 2020 02:01:47

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 14:40:36
User entered 'Day 5'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:20

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-20T20:31:25', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '1647a088-bacb-4a30-8503-6a92a457ddcb' User entered 'None (0)'	System	21 Sep 2020 01:32:01

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:20

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-20T20:31:29', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '1647a088-bacb-4a30-8503-6a92a457ddcb' User entered 'None (0)'	System	21 Sep 2020 01:32:01

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-20T20:31:34', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '1647a088-bacb-4a30-8503-6a92a457ddcb' User entered 'None (0)'	System	21 Sep 2020 01:32:01
	System	21 Sep 2020 01:32:01

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-20T20:31:38', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '1647a088-bacb-4a30-8503-6a92a457ddcb' User entered 'None (0)'	System	21 Sep 2020 01:32:01
	System	21 Sep 2020 01:32:01

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-20T20:31:41', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '1647a088-bacb-4a30-8503-6a92a457ddcb' User entered 'None (0)'	System	21 Sep 2020 01:32:01

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:20

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-20T20:31:44', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '1647a088-bacb-4a30-8503-6a92a457ddcb' User entered 'None (0)'	System	21 Sep 2020 01:32:01
	System	21 Sep 2020 01:32:01

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:20

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 (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-20T20:31:49', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '1647a088-bacb-4a30-8503-6a92a457ddcb' User entered 'No (N)'	System	21 Sep 2020 01:32:01

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:20

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-20T20:31:58', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '1647a088-bacb-4a30-8503-6a92a457ddcb' User entered '20 Sep 2020 20:31'	System	21 Sep 2020 01:32:01

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 14:40:36
User entered 'Day 6'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 14:40:36
User entered 'Day 7'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:20

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-22T20:50:01', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'd4e3463d-5e1b-4983-b71f-d76a5810df33'	System	23 Sep 2020 01:50:48
User entered 'None (0)'	System	23 Sep 2020 01:50:48

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:20

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-22T20:50:07', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'd4e3463d-5e1b-4983-b71f-d76a5810df33'	System	23 Sep 2020 01:50:48
User entered 'None (0)'	System	23 Sep 2020 01:50:48

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-22T20:50:11', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'd4e3463d-5e1b-4983-b71f-d76a5810df33'	System	23 Sep 2020 01:50:48
User entered 'None (0)'	System	23 Sep 2020 01:50:48

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-22T20:50:16', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'd4e3463d-5e1b-4983-b71f-d76a5810df33'	System	23 Sep 2020 01:50:48
User entered 'None (0)'	System	23 Sep 2020 01:50:48

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-22T20:50:19', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'd4e3463d-5e1b-4983-b71f-d76a5810df33'	System	23 Sep 2020 01:50:48
User entered 'None (0)'	System	23 Sep 2020 01:50:48

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:20

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-22T20:50:22', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'd4e3463d-5e1b-4983-b71f-d76a5810df33'	System	23 Sep 2020 01:50:48
User entered 'None (0)'	System	23 Sep 2020 01:50:48

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:20

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 (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-22T20:50:27', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'd4e3463d-5e1b-4983-b71f-d76a5810df33'	System	23 Sep 2020 01:50:48
User entered 'No (N)'	System	23 Sep 2020 01:50:48

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:20

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-09-22T20:50:33', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'd4e3463d-5e1b-4983-b71f-d76a5810df33'	System	23 Sep 2020 01:50:48
User entered '22 Sep 2020 20:50'	System	23 Sep 2020 01:50:48

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 14:40:36

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 01:50:17
User entered 'Day 8'	System	23 Sep 2020 01:50:17

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 12:00'	System	23 Sep 2020 01:50:17

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 01:50:17

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(9)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 01:50:17
User entered 'Day 9'	System	23 Sep 2020 01:50:17

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(9)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 01:50:17

US3752153

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(9)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 01:50:17

US3752153

Folder: Diary Dose 2 (1)

Form: Redness_Day(8)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 01:50:17
User entered 'Day 8'	System	23 Sep 2020 01:50:17

US3752153

Folder: Diary Dose 2 (1)

Form: Redness_Day(8)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 12:00'	System	23 Sep 2020 01:50:17

US3752153

Folder: Diary Dose 2 (1)

Form: Redness_Day(8)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 01:50:17

US3752153

Folder: Diary Dose 2 (1)

Form: Redness_Day(9)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 01:50:17
User entered 'Day 9'	System	23 Sep 2020 01:50:17

US3752153

Folder: Diary Dose 2 (1)

Form: Redness_Day(9)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 01:50:17

US3752153

Folder: Diary Dose 2 (1)

Form: Redness_Day(9)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 01:50:17

US3752153

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 01:50:17
User entered 'Day 8'	System	23 Sep 2020 01:50:17

US3752153

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 12:00'	System	23 Sep 2020 01:50:17

US3752153

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 01:50:17

US3752153

Folder: Diary Dose 2 (1)

Form: Swelling_Day(9)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 01:50:17
User entered 'Day 9'	System	23 Sep 2020 01:50:17

US3752153

Folder: Diary Dose 2 (1)

Form: Swelling_Day(9)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 01:50:17

US3752153

Folder: Diary Dose 2 (1)

Form: Swelling_Day(9)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 01:50:17

US3752153

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 01:50:17
User entered 'Day 8'	System	23 Sep 2020 01:50:17

US3752153

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 12:00'	System	23 Sep 2020 01:50:17

US3752153

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 01:50:17

US3752153

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	23 Sep 2020 01:50:17
User entered 'Day 9'	System	23 Sep 2020 01:50:17

US3752153

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 11:15:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 01:50:17

US3752153

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 11:15:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 01:50:17

US3752153

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 18:59:42

US3752153

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:20

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Sep 2020'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 18:59:42

US3752153

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 18:59:42

US3752153

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 18:59:42

US3752153

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 17:59:54

US3752153

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:20

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 17:59:54

US3752153

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 18:59:51

US3752153

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:20

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 18:59:51

US3752153

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 18:59:51

US3752153

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Amanda Horn (b) (4) (b) (4)	30 Oct 2020 18:59:51

US3752153

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 18:00:06

US3752153

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:20

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 18:00:06

US3752153

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 18:00:25

US3752153

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:20

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '7 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 18:00:25

US3752153

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	07 Oct 2020 18:00:25

US3752153

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 18:00:25

US3752153

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 18:39:52

US3752153

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:20

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 18:39:52

US3752153

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 18:40:13

US3752153

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:20

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 18:40:13

US3752153

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:20

[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 18:40:13

US3752153

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:15:20

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	13 Oct 2020 18:40:13

US3752153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 18:40:48

US3752153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:20

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 18:40:48

US3752153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:20

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '11:35'	(b) (4), (b) (6)	13 Oct 2020 18:40:48

US3752153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:20

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 11:35'	System	13 Oct 2020 18:40:48

US3752153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:20

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.3' F	(b) (4), (b) (6)	13 Oct 2020 18:40:48

US3752153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:20

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	13 Oct 2020 18:40:48

US3752153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:20

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 18:40:48

US3752153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '67'	(b) (4), (b) (6)	13 Oct 2020 18:40:48

US3752153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:20

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	13 Oct 2020 18:40:48

US3752153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:20

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	13 Oct 2020 18:40:48

US3752153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	13 Oct 2020 18:40:48

US3752153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:20

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '140'	(b) (4), (b) (6)	13 Oct 2020 18:40:48

US3752153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Oct 2020 18:40:48

US3752153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:20

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '74'	(b) (4), (b) (6)	13 Oct 2020 18:40:48

US3752153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:15:20

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Oct 2020 18:40:48

US3752153

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 18:40:56

US3752153

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:15:20

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '12 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 18:40:56

US3752153

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 18:41:16

US3752153

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:20

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 18:41:16

US3752153

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:20

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '11:42'	(b) (4), (b) (6)	13 Oct 2020 18:41:16

US3752153

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:15:20

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '12 Oct 2020 11:42'	System	13 Oct 2020 18:41:16

US3752153

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 18:41:30

US3752153

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:20

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 18:41:30

US3752153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 17:54:51
User entered 'Day 64'	System	19 Aug 2020 17:54:51

US3752153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

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 (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-10-19T13:49:33', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'f677d32d-3daf-47d4-a1a7-e4b6703bb077'	System	19 Oct 2020 18:50:10
User entered 'No (N)'	System	19 Oct 2020 18:50:10

US3752153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

Have you been exposed to someone with 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 (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-10-19T13:49:42', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'f677d32d-3daf-47d4-a1a7-e4b6703bb077'	System	19 Oct 2020 18:50:10
User entered 'No (N)'	System	19 Oct 2020 18:50:10

US3752153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-10-19T13:50:07', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: 'f677d32d-3daf-47d4-a1a7-e4b6703bb077' User entered '19 Oct 2020 13:50:07'	System	19 Oct 2020 18:50:10
	System	19 Oct 2020 18:50:10

US3752153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 17:54:51
User entered '19 Oct 2020 00:01'	System	19 Aug 2020 17:54:51

US3752153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 17:54:51
User entered '23 Oct 2020 23:59'	System	19 Aug 2020 17:54:51

US3752153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 17:54:51
User entered 'Day 71'	System	19 Aug 2020 17:54:51

US3752153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[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 (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-10-29T08:07:10', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '41c51d61-a18c-4ec3-a53c-8970361cd023' User entered 'No (N)'	System	29 Oct 2020 13:07:57
	System	29 Oct 2020 13:07:57

US3752153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

Have you been exposed to someone with 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 (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-10-29T08:07:31', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '41c51d61-a18c-4ec3-a53c-8970361cd023'	System	29 Oct 2020 13:07:57
User entered 'No (N)'	System	29 Oct 2020 13:07:57

US3752153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C2CC6FB5-144E-4452-BAC4-071A1ABD945A)', Time: '2020-10-29T08:07:52', User OID: 'PatientReportedOutcome (US3752153)', ODM File OID: '41c51d61-a18c-4ec3-a53c-8970361cd023' User entered '29 Oct 2020 08:07:52'	System	29 Oct 2020 13:07:57
	System	29 Oct 2020 13:07:57

US3752153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 17:54:51
User entered '26 Oct 2020 00:01'	System	19 Aug 2020 17:54:51

US3752153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	19 Aug 2020 17:54:51
User entered '30 Oct 2020 23:59'	System	19 Aug 2020 17:54:51

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '16 Oct 2020 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '20 Oct 2020 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '23 Oct 2020 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '27 Oct 2020 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '30 Oct 2020 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '03 Nov 2020 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '06 Nov 2020 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '10 Nov 2020 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '13 Nov 2020 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '17 Nov 2020 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '21 Oct 2022 00:01'	System	19 Nov 2020 23:01:26

US3752153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:15:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:01:26
Amendment Manager: User entered '25 Oct 2022 23:59'	System	19 Nov 2020 23:01:26

US3752153

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 17:29:10

US3752153

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:20

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '9 Nov 2020'	(b) (4), (b) (6)	09 Nov 2020 17:29:10

US3752153

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	09 Nov 2020 17:29:10

US3752153

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:15:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	09 Nov 2020 17:29:10

US3752153

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Nov 2020 17:29:15

US3752153

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:15:20

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Nov 2020 17:29:15

US3752153

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:15:20

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 18:47:22
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 21:24:41

US3752153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:20

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site swelling, LLT: Injection site swelling - version MedDRA\23.0.	Coder Import (b) (4)	14 Oct 2020 13:29:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	14 Oct 2020 13:29:31
Data point term sent to Coder	System	14 Oct 2020 13:28:48
User closed query 'DM-Coding: Please provide a unifying diagnosis for this reported event or split to report each event into a separate record, example: 1) LEFT ARM INJECTION SITE SWELLING 2) LEFT ARM INJECTION SITE REDNESS etc.' (Site from System).	System	14 Oct 2020 13:28:04
Query 'DM-Coding: Please provide a unifying diagnosis for this reported event or split to report each event into a separate record, example: 1) LEFT ARM INJECTION SITE SWELLING 2) LEFT ARM INJECTION SITE REDNESS etc.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	14 Oct 2020 13:28:04
User entered 'LEFT ARM INJECTION SITE SWELLING' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 13:27:53
User opened query 'DM-Coding: Please provide a unifying diagnosis for this reported event or split to report each event into a separate record, example: 1) LEFT ARM INJECTION SITE SWELLING 2) LEFT ARM INJECTION SITE REDNESS etc.' (Site from System).	Coder Import (b) (4)	14 Oct 2020 05:54:20
Data point term sent to Coder	System	13 Oct 2020 18:52:47
User entered 'Left arm injection site swelling and redness'	(b) (4), (b) (6)	13 Oct 2020 18:51:50

US3752153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:20

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 18:51:50

US3752153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:20

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 18:51:50

US3752153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:20

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 18:51:50

US3752153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:20

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020'	(b) (4), (b) (6)	13 Oct 2020 18:51:50

US3752153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:20

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	14 Oct 2020 13:05:46
Query 'Data is required. Please provide.' answered with 'unknown time' (Site from System).	(b) (4), (b) (6)	13 Oct 2020 18:52:07
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 18:51:50
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 18:51:50

US3752153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:20

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 18:51:50

US3752153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:20

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 18:51:50

US3752153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:20

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '25 Sep 2020'	(b) (4), (b) (6)	13 Oct 2020 18:51:50

US3752153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:20

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	14 Oct 2020 13:05:49
Query 'Data is required. Please provide.' answered with 'unknown time' (Site from System).	(b) (4), (b) (6)	13 Oct 2020 18:52:15
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 18:51:50
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 18:51:50

US3752153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:20

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 18:51:50

US3752153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:20

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	13 Oct 2020 18:51:50

US3752153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:20

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	13 Oct 2020 18:52:28
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 18:52:28
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	13 Oct 2020 18:51:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 18:51:50

US3752153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:20

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 18:51:50

US3752153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:20

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 18:51:50

US3752153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 18:51:50

US3752153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:20

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 18:51:50

US3752153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:20

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 18:51:50

US3752153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:20

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 18:51:50

US3752153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:20

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 18:51:50

US3752153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 18:51:50

US3752153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 18:51:50

US3752153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:20

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 18:51:50

US3752153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:20

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)'	(b) (4), (b) (6)	13 Oct 2020 18:51:50

US3752153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:20

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)'	(b) (4), (b) (6)	13 Oct 2020 18:51:50

US3752153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:20

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	(b) (4), (b) (6)	13 Oct 2020 18:51:50

US3752153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:20

[None](#)

Audit	User	Time (GMT)
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 14:43:23
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	13 Oct 2020 18:53:55
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 18:53:55
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	13 Oct 2020 18:51:50
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 18:51:50

US3752153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:20

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 14:43:23
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 18:51:50

US3752153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:20

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 18:51:50

US3752153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:20

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	13 Oct 2020 18:51:50

US3752153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:20

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 18:51:50

US3752153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:20

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	13 Oct 2020 18:52:28
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	13 Oct 2020 18:52:28
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	13 Oct 2020 18:51:50
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 18:51:50

US3752153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:20

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	13 Oct 2020 18:52:28
User entered '1'	System	13 Oct 2020 18:51:50

US3752153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:15:20

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Oct 2020 18:51:50

US3752153

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:20

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site pain, LLT: Injection site pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 18:56:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 18:56:22
Data point term sent to Coder	System	13 Oct 2020 18:55:52
User entered 'Left arm injection site pain'	(b) (4), (b) (6) (b) (4)	13 Oct 2020 18:55:14

US3752153

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:20

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 18:55:14

US3752153

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:20

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 18:55:14

US3752153

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:20

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 18:55:14

US3752153

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:20

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	14 Oct 2020 13:05:25
User entered '17 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 18:57:49
Query 'Data is required. Please complete.' answered with 'unknown time' (Site from System).	(b) (4), (b) (6)	13 Oct 2020 18:55:37
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 18:55:14
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 18:55:14

US3752153

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:20

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	14 Oct 2020 13:05:30
Query 'Data is required. Please provide.' answered with 'time unknown' (Site from System).	(b) (4), (b) (6)	13 Oct 2020 18:57:57
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 18:57:49
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 18:55:14

US3752153

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:20

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 18:55:14

US3752153

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:20

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 18:55:14

US3752153

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:20

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '25 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 18:57:49
User entered '17 Sep 2020'	(b) (4), (b) (6)	13 Oct 2020 18:55:14

US3752153

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:20

End time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	14 Oct 2020 13:05:34
Query 'Data is required. Please provide.' answered with 'time unknown' (Site from System).	(b) (4), (b) (6)	13 Oct 2020 18:58:03
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 18:57:49
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 18:55:14

US3752153

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:20

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 18:55:14

US3752153

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:20

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	13 Oct 2020 18:55:14

US3752153

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:20

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 18:55:14

US3752153

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:20

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 18:55:14

US3752153

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:20

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 18:55:14

US3752153

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 18:55:14

US3752153

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:20

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 18:55:14

US3752153

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:20

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 18:55:14

US3752153

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:20

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 18:55:14

US3752153

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:20

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 18:55:14

US3752153

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 18:55:14

US3752153

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 18:55:14

US3752153

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:20

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 18:55:14

US3752153

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:20

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)'	(b) (4), (b) (6)	13 Oct 2020 18:55:14

US3752153

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:20

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)'	(b) (4), (b) (6)	13 Oct 2020 18:55:14

US3752153

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:20

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	(b) (4), (b) (6)	13 Oct 2020 18:55:14

US3752153

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:20

[None](#)

Audit	User	Time (GMT)
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	13 Oct 2020 18:55:48
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 18:55:48
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	13 Oct 2020 18:55:14
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 18:55:14

US3752153

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:20

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 18:55:14

US3752153

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:20

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 18:55:14

US3752153

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:20

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	13 Oct 2020 18:55:14

US3752153

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:20

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 18:55:14

US3752153

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:20

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 18:55:14

US3752153

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:20

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	13 Oct 2020 18:55:14

US3752153

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 11:15:20

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Oct 2020 18:55:14

US3752153

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:20

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Was this a Solicited Adverse Reaction? = Yes. However, Injection Site Induration is not a solicited event for this study. Please review and update response to 'Was this a Solicited Adverse Reaction?' as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 17:15:07
Query 'Per DM CLR: Was this a Solicited Adverse Reaction? = Yes. However, Injection Site Induration is not a solicited event for this study. Please review and update response to 'Was this a Solicited Adverse Reaction?' as appropriate. Otherwise, clarify.' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 16:46:06
User opened query 'Per DM CLR: Was this a Solicited Adverse Reaction? = Yes. However, Injection Site Induration is not a solicited event for this study. Please review and update response to 'Was this a Solicited Adverse Reaction?' as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 14:50:03
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site induration, LLT: Injection site induration - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 04:51:26
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 04:51:26
Data point term sent to Coder	System	13 Oct 2020 18:57:57
User entered 'Left arm injection site induration'	(b) (4), (b) (6)	13 Oct 2020 18:56:57

US3752153

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:20

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 18:56:57

US3752153

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:20

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Nov 2020 16:45:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 18:56:57

US3752153

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:20

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 18:56:57

US3752153

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:20

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020'	(b) (4), (b) (6)	13 Oct 2020 18:56:57

US3752153

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:20

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	14 Oct 2020 13:05:09
Query 'Data is required. Please provide.' answered with 'unknown time' (Site from System).	(b) (4), (b) (6)	13 Oct 2020 18:57:04
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 18:56:57
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 18:56:57

US3752153

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:20

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 18:56:57

US3752153

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:20

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 18:56:57

US3752153

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:20

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '25 Sep 2020'	(b) (4), (b) (6)	13 Oct 2020 18:56:57

US3752153

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:20

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	14 Oct 2020 13:05:14
Query 'Data is required. Please provide.' answered with 'unknown time' (Site from System).	(b) (4), (b) (6)	13 Oct 2020 18:57:10
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 18:56:57
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 18:56:57

US3752153

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:20

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 18:56:57

US3752153

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:20

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	13 Oct 2020 18:56:57

US3752153

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:20

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 18:56:57

US3752153

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:20

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 18:56:57

US3752153

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:20

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 18:56:57

US3752153

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 18:56:57

US3752153

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:20

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 18:56:57

US3752153

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:20

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 18:56:57

US3752153

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:20

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 18:56:57

US3752153

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:20

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 18:56:57

US3752153

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 18:56:57

US3752153

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 18:56:57

US3752153

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:20

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 18:56:57

US3752153

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:20

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)'	(b) (4), (b) (6)	13 Oct 2020 18:56:57

US3752153

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:20

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)'	(b) (4), (b) (6)	13 Oct 2020 18:56:57

US3752153

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:20

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	(b) (4), (b) (6)	13 Oct 2020 18:56:57

US3752153

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:20

None

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE during this time frame. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 17:15:14
Query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE during this time frame. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 16:46:16
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Nov 2020 16:45:56
User opened query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE during this time frame. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 14:50:35
User entered '1'	(b) (4), (b) (6)	13 Oct 2020 18:56:57

US3752153

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:20

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Nov 2020 16:45:56
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 18:56:57

US3752153

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:20

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 18:56:57

US3752153

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:20

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	13 Oct 2020 18:56:57

US3752153

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:20

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 18:56:57

US3752153

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:20

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 18:56:57

US3752153

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:20

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	13 Oct 2020 18:56:57

US3752153

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 11:15:20

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Oct 2020 18:56:57

US3752153

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:20

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review and reflect the specific Type (e.g., Macular, Papular, etc) of REDNESS and if this is Urticarial or Non-Urticarial. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 17:15:29
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site erythema, LLT: Injection site redness - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 22:11:39
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 22:11:39
Data point term sent to Coder	System	03 Nov 2020 14:31:37
Query 'Per DM CLR: Please review and reflect the specific Type (e.g., Macular, Papular, etc) of REDNESS and if this is Urticarial or Non-Urticarial. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 14:30:51
Coding entries removed.	(b) (4), (b) (6)	03 Nov 2020 14:30:42
User entered 'LEFT ARM INJECTION SITE REDNESS (type of redness unknown and unknown if urticarial or nonurticarial)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Nov 2020 14:30:42
User opened query 'Per DM CLR: Please review and reflect the specific Type (e.g., Macular, Papular, etc) of REDNESS and if this is Urticarial or Non-Urticarial. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 06:00:26
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site erythema, LLT: Injection site redness - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 14:43:31

US3752153

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:20

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	14 Oct 2020 14:43:31
User: (b) (6) version MedDRA\23.0.	(b) (4)	
Data point term sent to Coder	System	14 Oct 2020 13:29:49
User entered 'LEFT ARM INJECTION SITE REDNESS'	(b) (4), (b) (6)	14 Oct 2020 13:29:30

US3752153

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:20

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 13:29:30

US3752153

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:20

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 13:29:30

US3752153

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:20

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 13:29:30

US3752153

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:20

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020'	(b) (4), (b) (6)	14 Oct 2020 13:29:30

US3752153

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:20

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	19 Oct 2020 18:13:27
Query 'Data is required. Please provide.' answered with 'TIME IS UNKNOWN' (Site from System).	(b) (4), (b) (6)	14 Oct 2020 13:29:45
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Oct 2020 13:29:30
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 13:29:30

US3752153

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:20

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 13:29:30

US3752153

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:20

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 13:29:30

US3752153

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:20

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '25 Sep 2020'	(b) (4), (b) (6)	14 Oct 2020 13:29:30

US3752153

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:20

End time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	19 Oct 2020 18:13:29
Query 'Data is required. Please provide.' answered with 'TIME IS UNKNOWN' (Site from System).	(b) (4), (b) (6)	14 Oct 2020 13:29:59
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Oct 2020 13:29:30
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 13:29:30

US3752153

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:20

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 13:29:30

US3752153

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:20

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	14 Oct 2020 13:29:30

US3752153

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:20

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	14 Oct 2020 13:29:30

US3752153

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:20

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 13:29:30

US3752153

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:20

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 13:29:30

US3752153

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 13:29:30

US3752153

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:20

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 13:29:30

US3752153

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:20

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 13:29:30

US3752153

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:20

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 13:29:30

US3752153

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:20

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 13:29:30

US3752153

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 13:29:30

US3752153

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 13:29:30

US3752153

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:20

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 13:29:30

US3752153

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:20

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)'	(b) (4), (b) (6)	14 Oct 2020 13:29:30

US3752153

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:20

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	14 Oct 2020 13:29:30

US3752153

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:20

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	(b) (4), (b) (6)	14 Oct 2020 13:29:30

US3752153

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:20

[None](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	14 Oct 2020 13:29:30

US3752153

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:20

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 13:29:30

US3752153

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:20

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	14 Oct 2020 13:29:30

US3752153

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:20

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 13:30:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Oct 2020 13:30:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 13:30:12
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 13:29:30
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 13:29:30

US3752153

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:20

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 13:29:30

US3752153

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:20

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Oct 2020 13:29:30

US3752153

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:20

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Oct 2020 13:29:30

US3752153

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 11:15:20

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Oct 2020 13:29:30

US3752153

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:20

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review if this is a worsening of the recorded MH condition of Osteoarthritis. If yes, please update to reflect worsening of osteoarthritis as applicable and ensure that the severity is greater than Grade 1/Mild. Please update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 16:14:00
User closed query 'Per DM CLR: Please review AE and please update to specify the location of Joint Aches. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 16:13:58
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis aggravated - version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 11:59:18
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4)	05 Nov 2020 11:59:18
Data point term sent to Coder	System	02 Nov 2020 16:49:36
Query 'Per DM CLR: Please review if this is a worsening of the recorded MH condition of Osteoarthritis. If yes, please update to reflect worsening of osteoarthritis as applicable and ensure that the severity is greater than Grade 1/Mild. Please update applicable details as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 16:49:20
User entered 'WORSENING OF OSTEOARTHRITIS (unknown location)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Nov 2020 16:49:14
User entered 'Worsening of osteoarthritis' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Nov 2020 16:48:36
Data point term sent to Coder	System	02 Nov 2020 16:48:36
Query 'Per DM CLR: Please review AE and please update to specify the location of Joint Aches. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' answered with 'unknown' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 16:48:07
Coding entries removed.	(b) (4), (b) (6)	02 Nov 2020 16:47:55
User entered 'JOINTS ACHE (unknown location)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Nov 2020 16:47:55

US3752153

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:20

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review if this is a worsening of the recorded MH condition of Osteoarthritis. If yes, please update to reflect worsening of osteoarthritis as applicable and ensure that the severity is greater than Grade 1/Mild. Please update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 14:49:22
User opened query 'Per DM CLR: Please review AE and please update to specify the location of Joint Aches. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 14:49:06
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Joint ache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 17:57:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 17:57:39
Data point term sent to Coder	System	14 Oct 2020 17:56:55
User entered 'JOINTS ACHE'	Amanda Horn (b) (4) (b) (4)	14 Oct 2020 17:56:28

US3752153

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:20

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	14 Oct 2020 17:56:28

US3752153

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:20

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Was this a Solicited Adverse Reaction? = Yes. However, this was not captured on the subject's Diary record and will be considered as Unsolicited event. Please review and update response to 'Was this a Solicited Adverse Reaction?' as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 17:15:51
Query 'Per DM CLR: Was this a Solicited Adverse Reaction? = Yes. However, this was not captured on the subject's Diary record and will be considered as Unsolicited event. Please review and update response to 'Was this a Solicited Adverse Reaction?' as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 16:48:32
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Nov 2020 16:47:55
User opened query 'Per DM CLR: Was this a Solicited Adverse Reaction? = Yes. However, this was not captured on the subject's Diary record and will be considered as Unsolicited event. Please review and update response to 'Was this a Solicited Adverse Reaction?' as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 14:49:42
User entered 'Yes (Y)'	Amanda Horn (b) (4)	14 Oct 2020 17:56:28

US3752153

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:20

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	14 Oct 2020 17:56:28

US3752153

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:20

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	Amanda Horn (b) (4) (b) (4)	14 Oct 2020 17:56:28

US3752153

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:20

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	20 Oct 2020 08:14:27
Query 'Data is required. Please provide.' answered with 'UNKNOWN START TIME' (Site from System).	Amanda Horn (b) (4)	14 Oct 2020 17:56:49
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Oct 2020 17:56:28
User entered empty.	Amanda Horn (b) (4)	14 Oct 2020 17:56:28

US3752153

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:20

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 17:56:28

US3752153

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:20

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	14 Oct 2020 17:56:28

US3752153

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:20

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '29 Aug 2020'	Amanda Horn (b) (4) (b) (4)	14 Oct 2020 17:56:28

US3752153

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:20

End time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	20 Oct 2020 08:14:32
Query 'Data is required. Please provide.' answered with 'UNKNOWN END TIME' (Site from System).	Amanda Horn (b) (4)	14 Oct 2020 17:56:56
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	14 Oct 2020 17:56:28
User entered empty.	System	14 Oct 2020 17:56:28
	Amanda Horn (b) (4)	14 Oct 2020 17:56:28
	(b) (4)	

US3752153

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:20

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Oct 2020 17:56:28

US3752153

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:20

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Amanda Horn (b) (4) (b) (4)	14 Oct 2020 17:56:28

US3752153

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:20

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	14 Oct 2020 17:56:28

US3752153

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:20

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Amanda Horn (b) (4) (b) (4)	14 Oct 2020 17:56:28

US3752153

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:20

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Amanda Horn (b) (4) (b) (4)	14 Oct 2020 17:56:28

US3752153

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Amanda Horn (b) (4) (b) (4)	14 Oct 2020 17:56:28

US3752153

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:20

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Amanda Horn (b) (4) (b) (4)	14 Oct 2020 17:56:28

US3752153

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:20

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Amanda Horn (b) (4) (b) (4)	14 Oct 2020 17:56:28

US3752153

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:20

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Amanda Horn (b) (4) (b) (4)	14 Oct 2020 17:56:28

US3752153

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:20

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Amanda Horn (b) (4) (b) (4)	14 Oct 2020 17:56:28

US3752153

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Amanda Horn (b) (4) (b) (4)	14 Oct 2020 17:56:28

US3752153

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Amanda Horn (b) (4) (b) (4)	14 Oct 2020 17:56:28

US3752153

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:20

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Amanda Horn (b) (4) (b) (4)	14 Oct 2020 17:56:28

US3752153

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:20

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)'	Amanda Horn (b) (4) (b) (4)	14 Oct 2020 17:56:28

US3752153

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:20

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)'	Amanda Horn (b) (4) (b) (4)	14 Oct 2020 17:56:28

US3752153

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:20

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Amanda Horn (b) (4) (b) (4)	14 Oct 2020 17:56:28

US3752153

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:20

[None](#)

Audit	User	Time (GMT)
User entered '1'	Amanda Horn (b) (4) (b) (4)	14 Oct 2020 17:56:28

US3752153

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:20

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Amanda Horn (b) (4) (b) (4)	14 Oct 2020 17:56:28

US3752153

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:20

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Amanda Horn (b) (4) (b) (4)	14 Oct 2020 17:56:28

US3752153

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:20

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Amanda Horn (b) (4)	14 Oct 2020 17:56:28

US3752153

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:20

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Amanda Horn (b) (4) (b) (4)	14 Oct 2020 17:56:28

US3752153

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:20

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Amanda Horn (b) (4) (b) (4)	14 Oct 2020 17:56:28

US3752153

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:20

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Oct 2020 17:56:28

US3752153

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 26 Nov 2020 11:15:20

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Oct 2020 17:56:28

US3752153

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:20

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 14:47:17
User entered 'USA-US113-2020-mRNA-1273-P301000012'	System	13 Nov 2020 14:46:40
User entered 'New'	(b) (4), (b) (6)	13 Nov 2020 14:46:40

US3752153

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:20

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please confirm if the surgery was pre-planned for a pre-existing condition that did not worsen after the study enrollment. If yes, please consider removing this as an event.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 18:35:02
User closed query 'PV Query: The event term is a procedure; please consider updating the event term to the final diagnosis that required the procedure (i.e. knee arthritis, knee fracture, etc) .' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 18:35:00
Query 'PV Query: The event term is a procedure; please consider updating the event term to the final diagnosis that required the procedure (i.e. knee arthritis, knee fracture, etc) .' answered with 'Osteoarthritis. ' (Site from Safety).	Haylee Rowe (b) (4) (b) (4)	23 Nov 2020 18:29:20
Query 'PV Query: Please confirm if the surgery was pre-planned for a pre-existing condition that did not worsen after the study enrollment. If yes, please consider removing this as an event.' answered with 'Osteoarthritis is the pre-existing condition. Per protocol, this is a SAE since subject was hospitalized. ' (Site from Safety).	Haylee Rowe (b) (4) (b) (4)	23 Nov 2020 18:29:13
User opened query 'PV Query: The event term is a procedure; please consider updating the event term to the final diagnosis that required the procedure (i.e. knee arthritis, knee fracture, etc) .' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 21:25:46
User opened query 'PV Query: Please confirm if the surgery was pre-planned for a pre-existing condition that did not worsen after the study enrollment. If yes, please consider removing this as an event.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 21:25:06
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Knee arthroplasty - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 21:24:37
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 21:24:37
Data point term sent to Coder	System	12 Nov 2020 21:05:23
User entered 'Total right knee arthroplasty requiring hospitalization'	Lauren Evans (b) (4)	12 Nov 2020 21:05:03

US3752153

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:20

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lauren Evans (b) (4)	12 Nov 2020 21:05:03

US3752153

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:20

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Lauren Evans (b) (4) [REDACTED]	12 Nov 2020 21:05:03

US3752153

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:20

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Lauren Evans (b) (4) [REDACTED]	12 Nov 2020 21:05:03

US3752153

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:20

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '10 Nov 2020'	Lauren Evans (b) (4)	12 Nov 2020 21:05:03

US3752153

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:20

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Lauren Evans (b) (4) [REDACTED]	12 Nov 2020 21:05:03

US3752153

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:20

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 21:05:03

US3752153

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:20

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Lauren Evans (b) (4) [REDACTED]	12 Nov 2020 21:05:03

US3752153

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:20

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '10 Nov 2020'	Lauren Evans (b) (4)	12 Nov 2020 21:05:03

US3752153

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:20

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Lauren Evans (b) (4) [REDACTED]	12 Nov 2020 21:05:03

US3752153

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:20

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 21:05:03

US3752153

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:20

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 4 (Grade 4)'	Lauren Evans (b) (4) [REDACTED]	12 Nov 2020 21:05:03

US3752153

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:20

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lauren Evans (b) (4) [REDACTED]	12 Nov 2020 21:05:03

US3752153

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:20

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Lauren Evans (b) (4) [REDACTED]	12 Nov 2020 21:05:03

US3752153

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:20

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Lauren Evans (b) (4) [REDACTED]	12 Nov 2020 21:05:03

US3752153

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '1'	Lauren Evans (b) (4)	12 Nov 2020 21:05:03

US3752153

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:20

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '10 Nov 2020'	Lauren Evans (b) (4) [REDACTED]	12 Nov 2020 21:05:03

US3752153

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:20

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '11 Nov 2020'	Lauren Evans (b) (4)	12 Nov 2020 21:05:03

US3752153

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:20

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Lauren Evans (b) (4) [REDACTED]	12 Nov 2020 21:05:03

US3752153

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:20

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Lauren Evans (b) (4) [REDACTED]	12 Nov 2020 21:05:03

US3752153

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Lauren Evans (b) (4) [REDACTED]	12 Nov 2020 21:05:03

US3752153

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Lauren Evans (b) (4) [REDACTED]	12 Nov 2020 21:05:03

US3752153

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:20

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Lauren Evans (b) (4) [REDACTED]	12 Nov 2020 21:05:03

US3752153

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:20

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Lauren Evans (b) (4)	12 Nov 2020 21:05:03

US3752153

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:20

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Lauren Evans (b) (4)	12 Nov 2020 21:05:03

US3752153

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:20

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Lauren Evans (b) (4)	12 Nov 2020 21:05:03

US3752153

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:20

[None](#)

Audit	User	Time (GMT)
User entered '0'	Lauren Evans (b) (4)	12 Nov 2020 21:05:03

US3752153

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:20

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Lauren Evans (b) (4) [REDACTED]	12 Nov 2020 21:05:03

US3752153

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:20

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Lauren Evans (b) (4) [REDACTED]	12 Nov 2020 21:05:03

US3752153

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:20

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Lauren Evans (b) (4)	12 Nov 2020 21:05:03

US3752153

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:20

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Lauren Evans (b) (4) [REDACTED]	12 Nov 2020 21:05:03

US3752153

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:20

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 18:34:57
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)	24 Nov 2020 18:34:55
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 18:34:54
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'N/A' (Site from Safety).	Haylee Rowe (b) (4)	23 Nov 2020 18:35:04
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'Negative COVID-19 PCR test preformed 06 NOV 2020.' (Site from Safety).	Haylee Rowe (b) (4)	23 Nov 2020 18:34:59
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'Osteoarthritis.' (Site from Safety).	Haylee Rowe (b) (4)	23 Nov 2020 18:30:01
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 21:25:33
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 21:25:24
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 21:24:32
User entered 'Subject had a total right knee arthroplasty that required an admission to the hospital'	Lauren Evans (b) (4)	12 Nov 2020 21:05:03

US3752153

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:20

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 21:05:03

US3752153

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:20

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 21:05:03

US3752153

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 26 Nov 2020 11:15:20

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Nov 2020 21:05:03

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:15:20

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 21:24:51

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:20

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: CITALOPRAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 21:28:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 21:28:09
Data point term sent to Coder	System	19 Aug 2020 21:26:34
User entered 'Citalopram'	(b) (4), (b) (6)	19 Aug 2020 21:25:42

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 21:25:42

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:20

[Indication](#)

Audit	User	Time (GMT)
User entered 'Depression'	(b) (4), (b) (6)	19 Aug 2020 21:25:42

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:20

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '20'	(b) (4), (b) (6)	19 Aug 2020 21:25:42

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:20

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Aug 2020 21:25:42

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 21:25:42

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:20

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Aug 2020 21:25:42

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 21:25:42

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:20

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 21:25:42

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 21:25:42

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:20

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:35:20
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 21:25:42
User entered 'un UNK 1990'	(b) (4), (b) (6)	19 Aug 2020 21:25:42

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 21:25:42

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:20

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 21:25:42

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:20

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 21:25:42

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 21:26:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Aug 2020 21:26:02
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 21:26:02
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 21:25:42
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 21:25:42

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 21:25:42

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 21:25:42

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:15:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 21:25:42

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:20

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 21:28:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 21:28:10
Data point term sent to Coder	System	19 Aug 2020 21:27:36
User entered 'Bupropion'	(b) (4), (b) (6)	19 Aug 2020 21:27:03

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 21:27:03

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:20

[Indication](#)

Audit	User	Time (GMT)
User entered 'Depression'	(b) (4), (b) (6)	19 Aug 2020 21:27:03

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:20

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '150'	(b) (4), (b) (6)	19 Aug 2020 21:27:03

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:20

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Aug 2020 21:27:03

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 21:27:03

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:20

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	(b) (4), (b) (6)	19 Aug 2020 21:27:03

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 21:27:03

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:20

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Aug 2020 21:27:03

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 21:27:03

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:20

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:35:20
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 21:27:03
User entered 'un UNK 2009'	(b) (4), (b) (6)	19 Aug 2020 21:27:03

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 21:27:03

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:20

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 21:27:03

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 21:27:03

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 21:27:03

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Aug 2020 21:27:03

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 21:27:03

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:15:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 21:27:03

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:20

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: CANNABIDIOL, PRODUCTSYNONYM: CBD OIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 21:29:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 21:29:11
Data point term sent to Coder	System	19 Aug 2020 21:28:39
User entered 'CBD oil'	(b) (4), (b) (6) (b) (4)	19 Aug 2020 21:28:00

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 21:28:00

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:20

[Indication](#)

Audit	User	Time (GMT)
User entered 'Osteoarthritis'	(b) (4), (b) (6)	19 Aug 2020 21:28:00

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:20

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	19 Aug 2020 21:28:00

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:20

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	(b) (4), (b) (6)	19 Aug 2020 21:28:00

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:20

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered 'application'	(b) (4), (b) (6)	19 Aug 2020 21:28:00

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:20

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Aug 2020 21:28:00

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 21:28:00

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:20

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Topical (TOPICAL)'	(b) (4), (b) (6)	19 Aug 2020 21:28:00

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 21:28:00

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:20

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:35:20
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 21:28:00
User entered 'un UNK 2019'	(b) (4), (b) (6)	19 Aug 2020 21:28:00

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 21:28:00

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:20

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 21:28:00

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:20

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 21:28:00

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 21:28:00

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 21:28:00

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 21:28:00

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:15:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 21:28:00

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:20

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 14:32:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 14:32:48
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	27 Oct 2020 14:31:29 27 Oct 2020 14:31:18
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 18:58:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 18:58:44
Data point term sent to Coder User entered 'IBUPROFEN'	System Amanda Horn (b) (4) (b) (4)	22 Sep 2020 18:57:58 22 Sep 2020 18:57:01

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	22 Sep 2020 18:57:01

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:20

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 14:31:27
User entered 'Osteoarthritis' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 14:31:18
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 07:41:17
User entered 'KNEE PAIN'	Amanda Horn (b) (4) (b) (4)	22 Sep 2020 18:57:01

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:20

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '200'	Amanda Horn (b) (4) (b) (4)	22 Sep 2020 18:57:01

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:20

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Amanda Horn (b) (4) (b) (4)	22 Sep 2020 18:57:01

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Amanda Horn (b) (4) (b) (4)	22 Sep 2020 18:57:01

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:20

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Amanda Horn (b) (4) (b) (4)	22 Sep 2020 18:57:01

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Amanda Horn (b) (4) (b) (4)	22 Sep 2020 18:57:01

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:20

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Amanda Horn (b) (4) (b) (4)	22 Sep 2020 18:57:01

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Amanda Horn (b) (4) (b) (4)	22 Sep 2020 18:57:01

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:20

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020'	Amanda Horn (b) (4) (b) (4)	22 Sep 2020 18:57:01

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Amanda Horn (b) (4) (b) (4)	22 Sep 2020 18:57:01

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:20

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	22 Sep 2020 18:57:01

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:20

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Amanda Horn (b) (4) (b) (4)	22 Sep 2020 18:57:01

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	22 Sep 2020 18:57:01

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	22 Sep 2020 18:57:01

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 18:57:01

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:15:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Sep 2020 18:57:01

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:20

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 13:54:21
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 13:54:21
Data point term sent to Coder	System	23 Nov 2020 18:25:38
Coding entries removed.	Haylee Rowe (b) (4) (b) (4)	23 Nov 2020 18:24:55
User entered 'ANNUAL FLU VACCINATION' reason for change: Data Entry Error	Haylee Rowe (b) (4) (b) (4)	23 Nov 2020 18:24:55
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 18:44:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 18:44:20
Data point term sent to Coder	System	13 Oct 2020 18:43:29
Coding entries removed.	(b) (4), (b) (6) (b) (4)	13 Oct 2020 18:43:02
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 21:51:48
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 21:51:48
Data point term sent to Coder	System	07 Oct 2020 18:03:19
User entered 'Seasonal influenza vaccine'	(b) (4), (b) (6) (b) (4)	07 Oct 2020 18:02:27

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 18:02:27

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:20

[Indication](#)

Audit	User	Time (GMT)
User entered 'Prophylaxis for influenza' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 18:43:02
User entered 'unknown'	(b) (4), (b) (6)	07 Oct 2020 18:02:27

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:20

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '0.5'	(b) (4), (b) (6)	07 Oct 2020 18:02:27

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:20

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mL (mL)'	(b) (4), (b) (6)	07 Oct 2020 18:02:27

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:20

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 18:02:27

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:20

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	(b) (4), (b) (6)	07 Oct 2020 18:02:27

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 18:02:27

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:20

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	07 Oct 2020 18:02:27

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 18:02:27

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:20

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 18:43:02
User entered '29 Sep 2020'	(b) (4), (b) (6)	07 Oct 2020 18:02:27

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 18:02:27

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:20

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 18:02:27

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:20

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '02 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 18:43:02
User entered '29 Sep 2020'	(b) (4), (b) (6)	07 Oct 2020 18:02:27

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 18:02:27

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 18:02:27

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 18:02:27

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 11:15:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 18:02:27

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:20

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PNEUMOCOCCAL VACCINES, PRODUCT: PNEUMOCOCCAL VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 20:04:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 20:04:10
Data point term sent to Coder Coding entries removed.	System Haylee Rowe (b) (4) (b) (4)	23 Nov 2020 18:26:40 23 Nov 2020 18:25:53
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PNEUMOCOCCAL VACCINES, PRODUCT: PNEUMOCOCCAL VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 05:29:31
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 05:29:31
Data point term sent to Coder User entered 'Pneumonia vaccine'	System (b) (4), (b) (6) (b) (6)	13 Oct 2020 18:45:33 13 Oct 2020 18:45:02

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 18:45:02

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:20

[Indication](#)

Audit	User	Time (GMT)
User entered 'PNEUMONIA PREVENTION' reason for change: Data Entry Error	Haylee Rowe (b) (4)	23 Nov 2020 18:25:53
User entered 'Prophylaxis for pneumonia'	(b) (4), (b) (6)	13 Oct 2020 18:45:02

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:20

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	13 Oct 2020 18:45:02

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:20

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	(b) (4), (b) (6)	13 Oct 2020 18:45:02

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:20

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered 'injection'	(b) (4), (b) (6)	13 Oct 2020 18:45:02

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:20

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	(b) (4), (b) (6)	13 Oct 2020 18:45:02

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 18:45:02

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:20

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	13 Oct 2020 18:45:02

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 18:45:02

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:20

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 18:45:02

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 18:45:02

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:20

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 18:45:02

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '02 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 18:45:02

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 18:45:02

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 18:45:02

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 18:45:02

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 11:15:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 18:45:02

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:20

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 05:52:13
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 05:52:13
Data point term sent to Coder Coding entries removed.	System Haylee Rowe (b) (4) (b) (4)	23 Nov 2020 18:26:39 23 Nov 2020 18:26:22
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 21:39:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 21:39:50
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6) (b) (4)	17 Nov 2020 21:38:50 17 Nov 2020 21:38:11
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 07:19:30
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 07:19:30
Data point term sent to Coder User entered 'Ibuprofen'	System (b) (4), (b) (6) (b) (4)	13 Oct 2020 18:47:39 13 Oct 2020 18:47:08

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 18:47:08

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:20

[Indication](#)

Audit	User	Time (GMT)
User entered 'LEFT ARM INJECTION SITE PAIN RELIEF' reason for change: Data Entry Error	Haylee Rowe (b) (4)	23 Nov 2020 18:26:22
User closed query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.	(b) (4)	
' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 15:36:20
Query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.	(b) (4), (b) (6)	19 Nov 2020 14:43:46
' answered with 'AE updated' (Site from DM).		
User entered 'INJECTION SITE PAIN' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Nov 2020 21:38:11
User opened query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.	(b) (4), (b) (6)	17 Nov 2020 11:15:48
' (Site from DM).		
User entered 'Injection site pain relief'	(b) (4), (b) (6)	13 Oct 2020 18:47:08

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:20

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '150'	(b) (4), (b) (6)	13 Oct 2020 18:47:08

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:20

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	13 Oct 2020 18:47:08

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:20

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 18:47:08

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:20

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	(b) (4), (b) (6)	13 Oct 2020 18:47:08

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 18:47:08

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:20

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	13 Oct 2020 18:47:08

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 18:47:08

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:20

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020'	(b) (4), (b) (6)	13 Oct 2020 18:47:08

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 18:47:08

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:20

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 18:47:08

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '25 Sep 2020'	(b) (4), (b) (6)	13 Oct 2020 18:47:08

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 18:47:08

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 18:47:08

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 18:47:08

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 11:15:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 18:47:08

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:20

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 18:48:34
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 18:48:34
Data point term sent to Coder	System	22 Oct 2020 19:59:12
User entered 'IBUPROFEN'	Amanda Horn (b) (4) (b) (4)	22 Oct 2020 19:58:18

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	22 Oct 2020 19:58:18

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:20

[Indication](#)

Audit	User	Time (GMT)
User entered 'TREAT KNEE PAIN'	Amanda Horn (b) (4) (b) (4)	22 Oct 2020 19:58:18

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:20

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '600'	Amanda Horn (b) (4) (b) (4)	22 Oct 2020 19:58:18

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:20

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Amanda Horn (b) (4) (b) (4)	22 Oct 2020 19:58:18

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Amanda Horn (b) (4) (b) (4)	22 Oct 2020 19:58:18

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:20

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Amanda Horn (b) (4) (b) (4)	22 Oct 2020 19:58:18

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Amanda Horn (b) (4) (b) (4)	22 Oct 2020 19:58:18

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:20

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Amanda Horn (b) (4) (b) (4)	22 Oct 2020 19:58:18

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Amanda Horn (b) (4) (b) (4)	22 Oct 2020 19:58:18

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:20

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020'	Amanda Horn (b) (4) (b) (4)	22 Oct 2020 19:58:18

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Amanda Horn (b) (4) (b) (4)	22 Oct 2020 19:58:18

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:20

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	22 Oct 2020 19:58:18

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:20

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '25 Aug 2020'	Amanda Horn (b) (4) (b) (4)	22 Oct 2020 19:58:18

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	22 Oct 2020 19:58:18

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 19:58:18

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 19:58:18

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 11:15:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Oct 2020 19:58:18

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:20

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Nov 2020 14:51:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Nov 2020 14:51:47
Data point term sent to Coder	System	12 Nov 2020 14:51:05
User entered 'ATORVASTATIN'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 14:50:23

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 14:50:23

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:20

[Indication](#)

Audit	User	Time (GMT)
User entered 'MIXED HYPERLIPIDEMIA'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 14:50:23

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:20

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '10'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 14:50:23

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:20

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 14:50:23

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 14:50:23

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:20

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 14:50:23

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 14:50:23

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:20

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 14:50:23

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 14:50:23

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:20

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '2 Nov 2020'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 14:50:23

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 14:50:23

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:20

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 14:50:23

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:20

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 14:50:23

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Amanda Horn (b) (4) (b) (4)	12 Nov 2020 14:50:23

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 14:50:23

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 14:50:23

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 11:15:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Nov 2020 14:50:23

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:20

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Nov 2020 23:39:45
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Nov 2020 23:39:45
Data point term sent to Coder	System	12 Nov 2020 21:17:36
User entered 'Aspirin'	Lauren Evans (b) (4) (b) (4)	12 Nov 2020 21:17:17

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Lauren Evans (b) (4)	12 Nov 2020 21:17:17

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:20

[Indication](#)

Audit	User	Time (GMT)
User entered 'post procedure prophylaxis of DVT'	Lauren Evans (b) (4)	12 Nov 2020 21:17:17

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:20

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '81'	Lauren Evans (b) (4)	12 Nov 2020 21:17:17

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:20

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Lauren Evans (b) (4)	12 Nov 2020 21:17:17

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Lauren Evans (b) (4) [REDACTED]	12 Nov 2020 21:17:17

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:20

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Lauren Evans (b) (4)	12 Nov 2020 21:17:17

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Lauren Evans (b) (4)	12 Nov 2020 21:17:17

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:20

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Lauren Evans (b) (4)	12 Nov 2020 21:17:17

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Lauren Evans (b) (4)	12 Nov 2020 21:17:17

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:20

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '10 Nov 2020'	Lauren Evans (b) (4)	12 Nov 2020 21:17:17

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Lauren Evans (b) (4) [REDACTED]	12 Nov 2020 21:17:17

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:20

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lauren Evans (b) (4)	12 Nov 2020 21:17:17

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:20

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Lauren Evans (b) (4)	12 Nov 2020 21:17:17

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lauren Evans (b) (4)	12 Nov 2020 21:17:17

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	12 Nov 2020 21:17:17

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 21:17:17

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 11:15:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Nov 2020 21:17:17

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:15:20

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FLUTICASONE FUROATE;VILANTEROL TRIFENATATE, PRODUCTSYNONYM: BREO ELLIPTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 00:25:43
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 00:25:43
Data point term sent to Coder	System	12 Nov 2020 21:19:50
User entered 'Fluticasone furoate- vilanterol (Breo-Ellipta)'	Lauren Evans (b) (4) (b) (4)	12 Nov 2020 21:18:57

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:15:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Lauren Evans (b) (4) [REDACTED]	12 Nov 2020 21:18:57

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:15:20

[Indication](#)

Audit	User	Time (GMT)
User entered 'asthma'	Lauren Evans (b) (4)	12 Nov 2020 21:18:57

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:15:20

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '100/25'	Lauren Evans (b) (4)	12 Nov 2020 21:18:57

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:15:20

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'ug (ug)'	Lauren Evans (b) (4)	12 Nov 2020 21:18:57

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:15:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Lauren Evans (b) (4)	12 Nov 2020 21:18:57

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:15:20

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Lauren Evans (b) (4)	12 Nov 2020 21:18:57

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:15:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Lauren Evans (b) (4) [REDACTED]	12 Nov 2020 21:18:57

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:15:20

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Lauren Evans (b) (4) [REDACTED]	12 Nov 2020 21:18:57

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:15:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Lauren Evans (b) (4)	12 Nov 2020 21:18:57

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:15:20

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '10 Nov 2020'	Lauren Evans (b) (4)	12 Nov 2020 21:18:57

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:15:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Lauren Evans (b) (4)	12 Nov 2020 21:18:57

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:15:20

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lauren Evans (b) (4)	12 Nov 2020 21:18:57

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:15:20

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Lauren Evans (b) (4) [REDACTED]	12 Nov 2020 21:18:57

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:15:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Lauren Evans (b) (4)	12 Nov 2020 21:19:03
User entered 'Yes (Y)'	Lauren Evans (b) (4)	12 Nov 2020 21:18:57

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:15:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 21:18:57

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:15:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 21:18:57

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 11:15:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Nov 2020 21:18:57

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:15:20

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN W/OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 04:26:39
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 Nov 2020 04:26:39
Data point term sent to Coder	System	12 Nov 2020 21:20:52
User entered 'Oxycodone/acetaminophen'	Lauren Evans (b) (4) (b) (4)	12 Nov 2020 21:20:04

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:15:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Lauren Evans (b) (4)	12 Nov 2020 21:20:04

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:15:20

[Indication](#)

Audit	User	Time (GMT)
User entered 'post procedure pain'	Lauren Evans (b) (4)	12 Nov 2020 21:20:04

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:15:20

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '7.5/325'	Lauren Evans (b) (4) [REDACTED]	12 Nov 2020 21:20:04

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:15:20

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Lauren Evans (b) (4)	12 Nov 2020 21:20:04

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:15:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Lauren Evans (b) (4)	12 Nov 2020 21:20:04

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:15:20

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Lauren Evans (b) (4)	12 Nov 2020 21:20:04

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:15:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Lauren Evans (b) (4) [REDACTED]	12 Nov 2020 21:20:04

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:15:20

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Lauren Evans (b) (4)	12 Nov 2020 21:20:04

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:15:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Lauren Evans (b) (4)	12 Nov 2020 21:20:04

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:15:20

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '10 Nov 2020'	Lauren Evans (b) (4)	12 Nov 2020 21:20:04

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:15:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Lauren Evans (b) (4) [REDACTED]	12 Nov 2020 21:20:04

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:15:20

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lauren Evans (b) (4)	12 Nov 2020 21:20:04

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:15:20

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Lauren Evans (b) (4) [REDACTED]	12 Nov 2020 21:20:04

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:15:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lauren Evans (b) (4)	12 Nov 2020 21:20:04

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:15:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 21:20:04

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:15:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 21:20:04

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 11:15:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 21:20:04

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:15:20

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Nov 2020 23:14:37
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Nov 2020 23:14:37
Data point term sent to Coder	System	12 Nov 2020 21:21:54
User entered 'Albuterol actuation inhaler'	Lauren Evans (b) (4) (b) (4)	12 Nov 2020 21:20:59

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:15:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Lauren Evans (b) (4) [REDACTED]	12 Nov 2020 21:20:59

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:15:20

[Indication](#)

Audit	User	Time (GMT)
User entered 'asthma'	Lauren Evans (b) (4)	12 Nov 2020 21:20:59

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:15:20

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '90'	Lauren Evans (b) (4) [REDACTED]	12 Nov 2020 21:20:59

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:15:20

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'ug (ug)'	Lauren Evans (b) (4)	12 Nov 2020 21:20:59

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:15:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Lauren Evans (b) (4)	12 Nov 2020 21:20:59

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:15:20

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Lauren Evans (b) (4)	12 Nov 2020 21:20:59

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:15:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Lauren Evans (b) (4) [REDACTED]	12 Nov 2020 21:20:59

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:15:20

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Lauren Evans (b) (4) [REDACTED]	12 Nov 2020 21:20:59

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:15:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Lauren Evans (b) (4)	12 Nov 2020 21:20:59

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:15:20

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '01 Jan 2020'	Lauren Evans (b) (4)	12 Nov 2020 21:20:59

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:15:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Lauren Evans (b) (4) [REDACTED]	12 Nov 2020 21:20:59

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:15:20

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lauren Evans (b) (4)	12 Nov 2020 21:20:59

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:15:20

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Lauren Evans (b) (4)	12 Nov 2020 21:20:59

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:15:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Lauren Evans (b) (4) [REDACTED]	12 Nov 2020 21:20:59

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:15:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 21:20:59

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:15:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 21:20:59

US3752153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 11:15:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 21:20:59

US3752153

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:15:20

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Lauren Evans (b) (4)	12 Nov 2020 21:12:15

US3752153

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:15:20

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '21 Oct 2020'	Lauren Evans (b) (4)	12 Nov 2020 21:14:16

US3752153

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:15:20

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'CT right knee without contrast'	Lauren Evans (b) (4)	12 Nov 2020 21:14:16

US3752153

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:15:20

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: CT RIGHT KNEE WITHOUT CONTRAST has Indication as Adverse Event. Please consider Diagnostic for this Indication.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 19:21:32
Query 'Per CDM: CT RIGHT KNEE WITHOUT CONTRAST has Indication as Adverse Event. Please consider Diagnostic for this Indication.' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 14:44:37
User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 14:44:29
User opened query 'Per CDM: CT RIGHT KNEE WITHOUT CONTRAST has Indication as Adverse Event. Please consider Diagnostic for this Indication.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 13:40:20
User entered 'Adverse Event (AE)'	Lauren Evans (b) (4)	12 Nov 2020 21:14:16

US3752153

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:15:20

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Lauren Evans (b) (4) [REDACTED]	12 Nov 2020 21:14:16

US3752153

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 11:15:20

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Nov 2020'	Lauren Evans (b) (4)	12 Nov 2020 21:15:15

US3752153

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 11:15:20

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'Mako right total knee arthroplasty'	Lauren Evans (b) (4)	12 Nov 2020 21:15:15

US3752153

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 11:15:20

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	Lauren Evans (b) (4)	12 Nov 2020 21:15:15

US3752153

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 11:15:20

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Lauren Evans (b) (4) [REDACTED]	12 Nov 2020 21:15:15

US3752153

Folder: SAE USA-US113-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:20

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 14:50:51
User entered 'USA-US113-2020-MRNA-1273-P301000012'	System	13 Nov 2020 14:46:40

US3752153

Folder: SAE USA-US113-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:20

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 14:50:51
User entered 'Yes (Y)'	System	13 Nov 2020 14:46:40

US3752153

Folder: SAE USA-US113-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:20

Death

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 14:50:51
User entered 'No (N)'	System	13 Nov 2020 14:46:40

US3752153

Folder: SAE USA-US113-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:20

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 14:50:51
User entered 'No (N)'	System	13 Nov 2020 14:46:40

US3752153

Folder: SAE USA-US113-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 14:50:51
User entered 'Yes (Y)'	System	13 Nov 2020 14:46:40

US3752153

Folder: SAE USA-US113-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 14:50:51
User entered 'No (N)'	System	13 Nov 2020 14:46:40

US3752153

Folder: SAE USA-US113-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 14:50:51
User entered 'No (N)'	System	13 Nov 2020 14:46:40

US3752153

Folder: SAE USA-US113-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:20

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 14:50:51
User entered 'No (N)'	System	13 Nov 2020 14:46:40

US3752153

Folder: SAE USA-US113-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:20

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 14:50:51
User entered 'Priyantha'	System	13 Nov 2020 14:46:40

US3752153

Folder: SAE USA-US113-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:20

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 14:50:51
User entered 'Wijewardane'	System	13 Nov 2020 14:46:40

US3752153

Folder: SAE USA-US113-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:20

[Investigator Country](#)

Audit	User	Time (GMT)
User entered 'US'	System	13 Nov 2020 14:51:03

US3752153

Folder: SAE USA-US113-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Nov 2020 14:51:03

US3752153

Folder: SAE USA-US113-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:20

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 14:50:51
User entered 'USA-US113-2020-MRNA-1273-P301000012'	System	13 Nov 2020 14:46:40

US3752153

Folder: SAE USA-US113-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:20

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 14:50:51
User entered 'Yes (Y)'	System	13 Nov 2020 14:46:40

US3752153

Folder: SAE USA-US113-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:20

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 14:50:51
User entered 'No (N)'	System	13 Nov 2020 14:46:40

US3752153

Folder: SAE USA-US113-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:20

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 14:50:51
User entered 'No (N)'	System	13 Nov 2020 14:46:40

US3752153

Folder: SAE USA-US113-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 14:50:51
User entered 'Yes (Y)'	System	13 Nov 2020 14:46:40

US3752153

Folder: SAE USA-US113-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 14:50:51
User entered 'No (N)'	System	13 Nov 2020 14:46:40

US3752153

Folder: SAE USA-US113-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 14:50:51
User entered 'No (N)'	System	13 Nov 2020 14:46:40

US3752153

Folder: SAE USA-US113-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:20

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 14:50:51
User entered 'No (N)'	System	13 Nov 2020 14:46:40

US3752153

Folder: SAE USA-US113-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:20

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 14:50:51
User entered 'Priyantha'	System	13 Nov 2020 14:46:40

US3752153

Folder: SAE USA-US113-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:20

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 14:50:51
User entered 'Wijewardane'	System	13 Nov 2020 14:46:40

US3752153

Folder: SAE USA-US113-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:20

[Investigator Country](#)

Audit	User	Time (GMT)
User entered 'US'	System	13 Nov 2020 14:51:03

US3752153

Folder: SAE USA-US113-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 26 Nov 2020 11:15:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Nov 2020 14:51:03

US3752153

Folder: SAE USA-US113-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:15:20

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '13/Nov/2020 14:50'	System	13 Nov 2020 14:51:03

US3752153

Folder: SAE USA-US113-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 11:15:20

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	13 Nov 2020 14:51:03